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> 0) 858-677-1400 F] 858-638-6727

OFFICE OF PETITIONS

December 4, 2001

Telephone:

Fax Number:

Examiner S. Brantley **USPTO** 

703-308-6916

From:

Terrance A. Meador 858-638-6747

**FAX TRANSMISSION COVER SHEET** 

Client-Matter Number:

AUGA01000010

Re:

Petition to Revive

U.S. Patent Application No. 08/419,719 filed 4/10/95

Pages: - 21 - (including this form)

Originals: □ will be mailed □ will not be mailed

If there is a problem with this transmission, please call (858) 667-1498

Fax Operator/Ext.

Marcia

#### Message:

Please find following a Petition and the associated documents for the above-referenced application.

- Petition dated 12/4/01
- Notice of Withdrawal from Issue (Paper No. 19), mailed 6/2/97
- Transmittal & Communication responsive to Paper No. 19, mailed 3/1/99
- Transmittal, Communication, Change of Address, IDS/1449, all dated 7/22/99
- Status Inquiry dated 9/11/00
- Three (3) USTPO stamped postcards
- Copy of Docket record

#### **CONFIDENTIALITY NOTICE**

This communication is ONLY for the person named above. Unless otherwise indicated, it contains information that is confidential, privileged or exempt from disclosure under applicable law. If you are not the person named above, or responsible for delivering it to that person, be aware that disclosure, copying, distribution or use of this communication is strictly PROHIBITED. If you have received it in error, or are uncertain as to its proper handling, please immediately notify us by collect telephone and mail the original to us at the above address. Thank you.

(Form Rev. 6/5/00)

Docket No.: AUGA01000010 Serial No.: 08/419,719 Filed: 04/10/95

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	)
Scott D. Augustine et al.	) Group No. 3904
Serial No.: 08/419,719	) Examiner: M. Graham
Filed: 04/10/95	) Docket No.: AUGA01000010
For: THERMAL BLANKET	

CERTIFICATION UNDER 37 CFR § 1.8

Thereby certify that this correspondence is being submitted via facsimile to the Commissioner of Patents and Trademarks, Washington, D.C. 20231, on this date: 

Date 4December 2001

Signature Lew Mul A. Mallol

Attention: Office of Petitions

BOX DAC

**Assistant Commissioner for Patents** 

Washington, D.C. 20231

RECEIVED

MAY 0 3 2002

OFFICE OF PETITIONS

ATTN: Examiner S. Brantley

# PETITION UNDER 37 CFR 1.183 FOR REVIVAL OF AN ABANDONED PATENT APPLICATION AND RECONSTRUCTION OF A MISSING FILE

The above-identified application became abandoned due to a failure by the United States Patent and Trademark Office to notify the applicant of action to be taken (if any).

#### APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION

This application was allowed by a notice of Allowance dated 02/03/97. The Issue Fee was paid by a transmittal mailed on 03/04/97. A Communication mailed on 10/21/97 informed the examiner of the entry of judgement on 09/26/97 in <u>Augustine Medical, Inc., v. Gaymar Industries</u> and in <u>Augustine Medical, Inc. v. Mallinckrodt Medical, Inc.</u> ("the litigation"). Augustine Medical, Inc. is the assignee of this application. On 11/17/97, an Information Disclosure Statement was submitted to disclose the merger of reexamination and reissue proceedings in US Patent No.

Gray Cary\GT\6266546.1 103806-153959 Docket No.: AUGA01000010 Serial No.: 08/419,719

Filed: 04/10/95

5,405,371. On 06/02/97, the Office mailed Paper # 19 in this application giving notice that the

application was being withdrawn from issue to reopen prosecution. A copy of that notice is

enclosed. No further communication respecting the reopening of prosecution has ever been

received by the applicant.

On 03/01/99, the applicant mailed a Communication requesting notice of the status of this

application, noting that a filing receipt in a related application (08/859,891) indicated that this

application had been abandoned. A copy of that Communication is enclosed, together with a copy

of a stamped postcard showing receipt of the Communication by the Office. Except for the

postcard, no response from the Office to the Communication of 03/01/99 was ever received.

On 07/22/99, the applicant submitted a Communication in this application that forwarded an

Information Disclosure Statement to disclose an update in the status of the litigation. A copy of

the Communication is enclosed, together with a copy of a stamped postcard showing receipt of

the Statement by the Office. Except for the postcard, no response from the Office to the

Communication of 07/22/99 was ever received.

The applicant submitted a Status Inquiry on 09/11/00 requesting the Office to notify the applicant

of the status of this application. A copy of the Status Inquiry is enclosed, together with a copy of

a stamped postcard showing receipt of the Status Inquiry by the Office. Except for the postcard,

no response from the Office to the Status Inquiry of 09/11/00 was ever received.

On or about 11/12/01, the undersigned held a telephonic interview with Examiner M. Graham

regarding the status of this application and seeking direction as to a course of action. The

examiner, who was most helpful, consulted the Office's internal application status database and

informed the undersigned that the database indicated the application was in indeed an abandoned

status and that the record further indicated the file had been lost.

With the exception of the return postcards already mentioned, no paper mailed by the Office

Gray Cary\GT\6266546.1 103806-153959

Docket No.:AUGA01000010

issue an appropriate paper.

Serial No.: 08/419,719 Filed: 04/10/95

(including a Notice of Abandonment) has been received in this application following the notice of withdrawal from issue. A copy of the docket record for this application is submitted in this regard.

In view of the lack of correspondence from the Office, the applicant has been unable to prosecute this application. If the application is, indeed, abandoned, the abandonment was both unavoidable and unintentional. However, the applicant cannot fulfill the conditions set forth in 37 CFR 1.137 for revival in either case, having no outstanding Office Action or Notice to respond to.

Accordingly, in the interest of doing justice in this case, the applicant respectfully requests that the Commissioner suspend the rules, revive the application, inform the applicant of the revival and

APPLICANT HEREBY PETITIONS FOR RECONSTRUCTION OF THIS FILE

If the file is lost and cannot be recovered or otherwise found, the applicant will make all file materials in its possession that are relevant to this application available for reconstruction of the file. In this regard, the applicant also petitions for reconstruction of the file.

If any fee is required, the Office is authorized to charge the fee to Deposit Account 07-1895 in the name of Gray Cary Ware & Freidenrich. In the event that the Commissioner determines that a fee is necessary, the undersigned respectfully requests notice of such.

Respectfully submitted

Date: 4 December 2001

TERRANCE A. MEADOR Reg. No. 30, 298

GRAY CARY WARE & FREIDENRICH 4365 Executive Drive, Suite 1100 San Diego, CA 92121-2133

Telephone: (858) 638-6747 Fax: (858) 638-6727

Gray Cary\GT\6266546.1 103806-153959

#### RECEIVED

JUN 04 1997

Rip

Baker, Maxham, Jester & Meach



UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

Paper No.19

TERRANCE A. MEADOR BAKER, MAXHAM, JESTER & MEADOR SYMPHONY TOWERS 750 "B" STREET, SUITE 3100 SAN DIEGO, CALIFORNIA 92101

ECEIVED COPY MAILED

MAY 0 3 2002

JUN 02 1997

OFFICE OF PETITIONS PATENT PUBLICATION

In re Application of Scott D. Augustine, et al. Application No. 08/419,719 Filed: April 10, 1995 Attorney Docket No. 1342-119

NOTICE

The purpose of this communication is to inform you that the above - identified application, which has received a patent number or an issue date, is being withdrawn from issue pursuant to 37 CFR 1.313.

The application is being withdrawn for the following purpose: to reopen prosecution. This withdrawal was requested by the Group Director. Any questions concerning this withdrawal should be addressed to the Group Director.

This application is being returned to the Office of the Director of Group 3300.

Telephone inquiries concerning this matter may be directed to the undersigned at (703) 308-5254.

Karna Cooper

Paralegal Specialist Office of the Director

Office of Patent Publication

DOCKETED

.IIIN - 4 1997

FILE 842-119 K

# RECEIVED MAY 0 3 2002 OFFICE OF PETITIONS

This USPTO date stamp hereon will acknowledge receipt of:

COMMUNICATION

Applican Assignee Serial No Filed:	: Augustine Medical, Inc.
Enclosur Mailed:	Form For Filing A Patent Application Under 37 CFR 1.60, Filing Receipt; and one return postcard.  MANMAGA
TAM/jiv	1000010
This USPTO d	ate stamp hereon will acknowledge receipt of:
COMMUNICA	TION
Applicant: Assignee: Serial No.: Filed:	Augustine et al Augustine Medical, Inc. 08/419,719 04/10/95
	Transmittal Form; copies of Notice, Request Form For Filing A Patent Application Under 37 CFR 1.60, Filing Receipt; and one return  MANUAGA
TAM/jiv	and the second
AUGA01000010 103806-153959	

PTO/SB/21 REV 1 (12/97)
Approved for use through 09/30/2000. omb 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

mation unless it displays a valid OMB control num		k Reduction Act of 1995, no	persons are required to respond to a collection of
manuff unicso it displays a rails are		Application Number	08/419,719
		Filing Date	04/10/95
TRANSMITTAL FO	RM	First Named Inventor	Augustine et al RECEIVED
(to be used for all correspondence after in		Examiner Name	Graham MAY 0 3 2002
		Group Art Unit	3304
otal Number of Pages in This Submission	7	Attorney Docket Number	AUGA01000010 OFFICE OF PETITIONS
	ENCLOSURES	(check all that apply)	۸,
Fee Transmittal Form	Assignment Pa	apers	After Allowance Communication to Group
Fee Attached Amendment/Response After Final Extension of Time Request Express Abandonment Request Information Disclosure Statement PTO Form 1449 (no.) cited references Certified Copy of Priority Document(s) Response to Missing Parts/ Incomplete Application PTO Form 1533 Response to Missing Parts		list and pelition plication ney, Revocation respondence Address aimer	Appeal Communication to Board of Appeals and Interferences  Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)  Proprietary Information  Status Letter  X. Additional Enclosure(s) (please identify below):  POSTCARD
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT  Firm or Reg. No. 30,298 Individual Name GRAY CARY WARE & FREIDENRICH  Signature  Date  CERTIFICATE OF MAILING  I hereby certify that this correspondence is being deposited with the United States Postal/Service as first class mail in an envelope addressed to:			
Assistant Commissioner for Patents, Washington,		10114/1/10 10	199
Typed or printed name Terrance A. Meador		<i>[</i>	
Signature Tenance	H Meda	W	Date /MAIM1999

PATENT

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE MAY 0 3 2002 OFFICE OF PETITIONS S.D. AUGUSTINE ET AL. Serial No.: 08/419,719 Filed: April 10, 1995 For: THERMAL BLANKET Assistant Commissioner for Patents Washington, D.C. 20231

ATTN: Mark Graham

Sir:

#### **COMMUNICATION**

On June 2, 1997, a Notice (Paper No. 19) was mailed from the Office of Patent Publication to the undersigned. A copy of the paper is attached. The purpose of the Paper was to give notice that the subject patent application was withdrawn from issue by the Office for the purpose of reopening prosecution. The Notice indicated the application was being returned to the Office of the Director of Group 3300. Since the June 2, 1997 Notice, we have received no further communication from the Patent Office regarding this matter.

On May 21, 1997, a Rule 60 Continuation was filed in this application. A copy of the Continuation Request is also attached. The Official Filing Receipt for this Continuation, copy attached, indicated that the subject application, Serial No. 08/419,719 had been abandoned. As evidenced by the Continuation Request, no abandonment was requested.

1

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The undersigned respectfully requests information as to the status of this application and the location of its file.

Respectfully submitted,

Date: 1/14/1999

TERRANCE A. MEADOR

Reg. No. 30,298

GRAY CARY WARE & FREIDENRICH 401 B Street, Suite 1700 San Diego, California 92101

Telephone (619) 699-2652 Fax (619) 236-1048

# RECEIVED

MAY 0 3 2002

## OFFICE OF PETITIONS

The USPTO date stamp hereon will acknowledge receipt of:

# SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicant:

Augustine et al

Assignee:

Augustine Medical, Inc.

Serial No.: Filed: 09/419,719 04/10/95

Enclosures:

Transmittal Form; PTO Form 1449; Two (2) cited

references; Change of Address; and one return

postcard: Communication

Mailed: 22 July 1999

TAM/jiv AUGA01000010 103806-153959

The USPTO date stamp hereon will acknowledge receipt of:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicant:

Augustine et al

Assignee: Serial No.: Augustine Medical, Inc. 09/419,719

Filed:

04/10/95

Enclosures:

Transmittal Form; PTO Form 1449; Two (2) cited references; Change of Address; and one return

postcard; Communication

Mailed: 22 July 1999

TAM/jiv AUGA01000010 103806-153959

PTO/SB/21 REV 1 (12/97)

227461999

Date

Approved for use through 09/30/2000. omb 0651-0032 Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of mation unless it displays a valid OMB control number. Application Number 08/419,719 04/10/95 Filing Date First Named Inventor Augustine et al TRANSMITTAL FORM (to be used for all correspondence after initial filing) Examiner Name Graham Group Art Unit 3304 OFFICE OF PETITIONS 5 + Post-card Attorney Docket Number AUGA01000010 stal Number of Pages in This Submission ENCLOSURES (check all that apply) Assignment Papers After Allowance Communication Fee Transmittal Form to Group (for an Application) Appeal Communication to Board \_ Fee Attached Drawing(s) of Appeals and Interferences Licensing-related Papers Amendment/Response Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) Petition Checklist and \_ After Final Accompanying Petition Proprietary Information Extension of Time Request To Convert a Communication Provisional Application Express Abandonment Request Additional Enclosure(s) Information Disclosure Statement Power of Attorney, Revocation (please identify below): x PTO Form 1449 Change of Correspondence Address 2 (no.) cited references POSTCARD Certified Copy of Priority Terminal Disclaimer Document(s) Response to Missing Parts/ Remarks: Incomplete Application PTO Form 1533 Response to Missing Parts Under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Terrance A. Meador Reg. No. 30,298 Individual Name GRAY CARY WARE & FREIDENRICH Signature Date CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: 22 Ju Assistant Commissioner for Patents, Washington, D.C. 20231 on this date: Typed or printed name Terrance A. Meador

Signature

Thomas

In re Applica	tion of:	)
S.D. AUGUS	TINE ET AL.	) Group Art Unit: 3304
Serial No.:	08/419,719	) Examiner: M. Graham
Filed:	April 10, 1995	) Docket No.: AUGA01000010
For: THEF	RMAL BLANKET	RECEIVED
Assistant Cor Washington,	numissioner for Patents D.C. 20231	MAY 0 3 2002 OFFICE OF PETITIONS
Sir:		- Ellions

#### REQUEST FOR CHANGE OF ADDRESS

This is to notify the Office that all correspondence in the subject matter should be addressed to:

TERRANCE A. MEADOR GRAY CARY WARE & FREIDENRICH 401 B STREET, SUITE 1700 SAN DIEGO, CALIFORNIA 92101

TELEPHONE - (619) 699-2652

Respectfully submitted,

Date: 22 July 1999

Terrance A. Meador Reg. No. 30,298

P:\FORMS\ADDRESS.CHG

In re Applica	tion of:	)	
S.D. AUGUS	STINE ET AL.	) Group Art Unit: 3304	
Serial No.:	08/419,719	) Examiner: M. Graham	
Filed:	April 10, 1995	) Docket No.: AUGA01000010	
For: THE	RMAL BLANKET	RECEIVE	D
Assistant Co.	mmissioner for Patents	MAY 0 3 2002	)

Assistant Commissioner for Patents Washington, D.C. 20231

OFFICE OF PETITIONS

Dear Sir:

#### COMMUNICATION

Accompanying this paper is an Information Disclosure Statement. On June 2, 1997, a Notice (Paper No. 19) was mailed from the Office of Patent Publication to the undersigned. The purpose of the Paper was to give notice that the subject patent application was withdrawn from issue by the Office for the purpose of reopening prosecution. The litigation related to the subject matter and priority of this application has now been heard on appeal by the Court of Appeals, Federal Circuit. The accompanying Information Disclosure Statement forwards a copy of the Decision on Appeal. Subsequent to the decision, Augustine Medical, Inc., the owner by assignment of this patent application, submitted a Petition For Rehearing And Suggestion For Rehearing In Banc, a copy of which is attached. As of this date, the Federal Circuit has not ruled on the Petition, but has asked that Gaymar and Mallinckrodt respond to the petition.

Respectfully submitted,

Date: 12 July 1999

inance A Mead Registration No. 30,298

GRAY CARY WARE & FREIDENRICH 401 B Street, Suite 1700 San Diego, California 92101

Telephone: (619) 699-2652 Fax: (619) 236-1048

In re Application of:	)
S.D. AUGUSTINE ET AL.	) Group Art Unit: 3304
Serial No.: 08/419,719	) Examiner: M. Graham
Filed: April 10, 1995	) Docket No.: AUGA01000010
For: THERMAL BLANKET	RECEIVED
Assistant Commissioner for Patents Washington, D.C. 20231	MAY 0 3 2002 OFFICE OF PETITIONS

Dear Sir:

#### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In satisfaction of their duty of candor and fair dealing, the applicants hereby cite the document listed on the accompanying Form PTO-1449 with respect to the above-identified patent application under the provisions of 37 CFR, 1.97(C) and 1.17(A). The Examiner is respectfully requested to make of record this documents if deemed relevant to the examination of this application.

Respectfully submitted,

TERRANCE A. MEADOR Registration No. 30,298

Date: 22 July 1999

GRAY CARY WARE & FREIDENRICH 401 B Street, Suite 1700 San Diego, California 92101

Telephone: (619) 699-2652 Fax: (619) 236-1048

P:\AUGUSTIN\153959.ID1

#### SHEET \_1\_ OF \_1 Application No. 08/419,719 Docket No. AUGA01000010 orm PTO-1449 INFORMATION DISCLOSURE CITATION Applicant: Augustine et al IN AN APPLICATION Group Art Unit 3304 Filing Date: 04/10/95 (Use Several Sheets If Necessary) U.S. PATENT DOCUMENTS FILING DATE IF APPROPRIATE CLASS SUBCLASS NAME DOCUMENT NUMBER DATE XAMINER INITIAL OFFICE OF PETITIONS FOREIGN PATENT DOCUMENTS TRANSLATION SUBCLASS CLASS COUNTRY DOCUMENT NUMBER DATE YES NO OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) US Court of Appeals For The Federal Circuit, DECISION, dated June 8, 1999, <u>Augustine Medical, Inc., vs. Gaymar Industries, Inc. and Medisearch PR. Inc., and Mallinckrodt Group, Inc. and Mallinckrodt Medical, Inc.</u>, 98-1001, -1002, -1054, -1244, -1266, June 8, 1999 US Court of Appeals For The Federal Circuit, COMBINED PETITION FOR REHEARING AND SUGGESTION FOR REHEARING IN BANC OF PLAINTIFF-CROSS-APPELLANT AUGUSTINE MEDICAL, INC., <u>Augustine Medical, Inc.</u>, <u>Gaymar Industries</u>, Inc. and Medisearch P R, Inc. and Mallinckrodt Group, Inc. and Mallinckrodt Medical, Inc., 94-CV-875, 94-CV-888, 96-CV-347 and 96-CV-1145, June 21, 1999

EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

DATE CONSIDERED

(2/92 PTO)

**EXAMINER** 

## RECEIVED

MAY 0 3 2002 OFFICE OF PETITIONS

The USPTO date stamp hereon will acknowledge receipt of:

CHANGENA WYDAAAA	STATUS INQUIRY
Serial No.:	08/419,719
Filed:	April 10, 1995
Mailed:	September / , 2000 O / P ( )   Sep 2 0 2000 E
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CHANGEKIA YODKESE	STATUS INQUIRY
Serial No.:	08/419,719
Filed:	
Mailed:	Santambar // 2000
TAM File No.:	AUGA01-10
cmr	

In re application of:	)
	) Group Art Unit: 3904
Augustine et al	)
	) Examiner: Graham
Serial No.: 08/419,719	)
	) Atty. Docket: AUGA01000010
Filed: April 10, 1995	) RECEIVED
	) ILCEIVED
For: THERMAL BLANKET	MAY 0 3 2002
	OFFICE OF PETITIONS

BOX: STATUS INQUIRY Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

#### STATUS INQUIRY LETTER

A Notice (Paper No. 19 mailed June 2, 1997) was sent from Ms. Karna Cooper informing that the subject application was being withdrawn from issue. Since that date no Correspondence has been received from the United States Patent and Trademark Office.

The applicants respectfully request the status of this case.

Respectfully submitted,

Date: 11 September 2000

TERRANCE A. MEADOR Attorney for Applicant Registration No. 30,298

GRAY CARY WARE & FREIDENRICH 401 B Street, Suite 1700 San Diego, California 92101

Telephone: (619) 699-2652 Fax: (619) 699-3952

P:\CLARE\STATUS.IN1

# RECEIVED MAY 0 3 2002 OFFICE OF PETITIONS

The USPTO date stamp hereon will acknowledge receipt of: CHANGENT ANDRESS STATUS INQUIRY 08/419,719 Serial No.:\_ April 10, 1995 September // , 2000 Mailed: \_ TAM AUGA01-10 File No.: THE OST TO date stamp hereon will acknowledge receipt or. CHANGEROF ANDRESS STATUS INQUIRY 08/419,719 Serial No.:\_ April 10, 1995 , 2000 September // Mailed: TAM AUGA01-10 File No.: cmr

In re application of:	)
Augustine et al	) Group Art Unit: 3904 ) Examiner: Graham
Serial No.: 08/419,719	) Atty. Docket: AUGA01000010
Filed: April 10, 1995	) .
For: THERMAL BLANKET	,
BOX: STATUS INQUIRY Assistant Commissioner for Patents Washington, D.C. 20231	RECEIVED  MAY 0 3 2002  OFFICE OF PETITIONS
Dear Sir:	Office a

#### STATUS INQUIRY LETTER

A Notice (Paper No. 19 mailed June 2, 1997) was sent from Ms. Karna Cooper informing that the subject application was being withdrawn from issue. Since that date no Correspondence has been received from the United States Patent and Trademark Office.

The applicants respectfully request the status of this case.

Respectfully submitted,

Date: 11 September 2000

TERRANCE A. MEADOR Attorney for Applicant Registration No. 30,298

GRAY CARY WARE & FREIDENRICH 401 B Street, Suite 1700 San Diego, California 92101

Telephone: (619) 699-2652 Fax: (619) 699-3952

P:\CLARE\STATUS.IN1

The USPTO date stamp hereon will acknowledge receipt of:

#### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicant:

Augustine et al

Assignee:

Augustine Medical, Inc.

Serial No.: Filed:

09/419,719 04/10/95

Enclosures:

Transmittal Form; PTO Form 1449; Two (2) cited

JUL 27

references; Change of Address; and one return

postcard: Communication

Mailed: 22 July 1999

RECEIVED

TAM/jiv AUGÃ01000010 MAY 0.3 2002

103806-153959

The USPTO date stamp hereon will acknowledge receipt of:

#### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicant:

Augustine et al

Assignee:

Augustine Medical, Inc.

Serial No.:

09/419,719

Filed:

04/10/95

Enclosures:

Transmittal Form; PTO Form 1449; Two (2) cited references; Change of Address; and one return

postcard: Communication

Mailed: 22 July 1999

TAM/jiv AUGA01000010 103806-153959

PTO/SB/21 REV 1 (12/97)
Approved for use through 09/30/2000. omb 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

mation unless it displays a	vatid OMB control n		k Reduction Act of 1995, no		
			Application Number	08/419,719	
		Filing Date	04/10/95		
TRANS	SMITTAL FO	ORM ·	First Named Inventor	Augustine et a	al Car
(to be used for a	all correspondence after	initial filing)	Examiner Name	Graham	
			Group Art Unit	3304	
al Number of Pages in Th	is Submission	5 + Postcard	Attorney Docket Number	AUGA010000	10
		· ENCLOSURES	(check all that apply)		
_ Fee Transmittal Form		Assignment Pa		After Allow to Group	ance Communication
Fee Attached		Drawing(s)			mmunication to Board
_ Amendment/Respons	e	Licensing-relat	ed Papers		and Interferences
After Final		Petition Check	list and		mmunication to Group e. Brief, Reply Brief)
Extension of Time Re	quest	Accompanying	Petition	Proprietary	Information
Express Abandonmer	nt Request	To Convert a Provisional Ap	plication ·	_x Communication _X_ Additional Enclosure(s)	
Information Disclosure			ney, Revocation		
_x PTO Form 1449 _2 (no.) cited refere	)		respondence Address	(please ide	nlify below):
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Incomplete Application		Remarks.			
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Response to Mis Under 37 CFR 1					
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		CERTIFICA	TE OF MAILING		
		deposited with the United	States Postal Service as firs	t class mail in an env	elope addressed to:
ped or printed name	Terrance A. Meador		1		
nature	Theman	A Mend		Date	22-Tul, 1999

In re Application of:		)	
S.D. AUGUS	TINE ET AL.	)	Group Art Unit: 3304
Serial No.:	08/419,719	)	Examiner: M. Graham
Filed:	April 10, 1995	)	Docket No.: AUGA01000010
For: THER	MAL BLANKET	,	

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

#### REQUEST FOR CHANGE OF ADDRESS

This is to notify the Office that all correspondence in the subject matter should be addressed to:

TERRANCE A. MEADOR GRAY CARY WARE & FREIDENRICH 401 B STREET, SUITE 1700 SAN DIEGO, CALIFORNIA 92101

TELEPHONE - (619) 699-2652

Respectfully submitted,

Date: 22 July 1999

Terrance A. Meador Reg. No. 30,298

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In re Application of:		)	
S.D. AUGU	STINE ET AL.	) Group Art Unit: 3304	
Serial No.:	08/419,719	) Examiner: M. Graham	
Filed:	April 10, 1995	) Docket No.: AUGA0	1000010
e mue	DAZAT DI ANEZET	,	

For: THERMAL BLANKET

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

#### COMMUNICATION

Accompanying this paper is an Information Disclosure Statement. On June 2, 1997, a Notice (Paper No. 19) was mailed from the Office of Patent Publication to the undersigned. The purpose of the Paper was to give notice that the subject patent application was withdrawn from issue by the Office for the purpose of reopening prosecution. The litigation related to the subject matter and priority of this application has now been heard on appeal by the Court of Appeals, Federal Circuit. The accompanying Information Disclosure Statement forwards a copy of the Decision on Appeal. Subsequent to the decision, Augustine Medical, Inc., the owner by assignment of this patent application, submitted a Petition For Rehearing And Suggestion For Rehearing In Banc, a copy of which is attached. As of this date, the Federal Circuit has not ruled on the Petition, but has asked that Gaymar and Mallinckrodt respond to the petition.

Respectfully submitted,

Date: 22 July 1999

TERRANCE A. MEADO Registration No. 30,298

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GRAY CARY WARE & FREIDENRICH 401 B Street, Suite 1700 San Diego, California 92101

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In re Applicat	ion of:	)	
S.D. AUGUS	TINE ET AL.	)	Group Art Unit: 3304
Serial No.:	08/419,719	)	Examiner: M. Graham
Filed:	April 10, 1995	)	Docket No.: AUGA01000010
For: THER	MAL BLANKET	,	·
Assistant Con Washington	nmissioner for Patents		

#### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In satisfaction of their duty of candor and fair dealing, the applicants hereby cite the document listed on the accompanying Form PTO-1449 with respect to the above-identified patent application under the provisions of 37 CFR, 1.97(C) and 1.17(A). The Examiner is respectfully requested to make of record this documents if deemed relevant to the examination of this application.

Respectfully submitted,

Date: 22 July 1999

Dear Sir:

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(2/92 PTO)

orm PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use Several Sheets If Necessary)			Docket No. AUG	GA01000010	Application No. 08/419,719				
			Applicant: Augustine et al						
			Filing Date: 04/10/95 Group Art Unit 3304						
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	US Court of Appea IN BANC OF PLAIN Inc. and Medisearc CV-347 and 96-CV	ITIFF-CROSS-A h P R. Inc. and	PPELLANT / Mallinckrod	AUGUSTINE MEDIC	AL, INC., Augu	stine Medical, Inc	. v. Gaymar	Industries.	
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not in conformance and not considered. Include copy of this form with next communication to the applicant.

# United States Court of Appeals for the Federal Circuit

98-1001, -1002,-1054,-1244,-1266

AUGUSTINE MEDICAL, INC.,

Plaintiff-Cross Appellant,

GAYMAR INDUSTRIES, INC. and MEDISEARCH P.R., INC.,

Defendants-Appellants,

and

MALLINCKRODT GROUP, INC. and MALLINCKRODT MEDICAL, INC.,

Defendants-Appellants.

DECIDED: June 8, 1999

Before MAYER, Chief Judge, RADER, and GAJARSA, Circuit Judges, RADER, Circuit Judge.

Augustine Medical, Inc. filed two separate lawsuits, one against Mallinckrodt Group, Inc. and Mallinckrodt Medical, Inc. (collectively, Mallinckrodt), and another against Gaymar Industries, Inc. and Medisearch P.R. Inc. (collectively, Gaymar). Each lawsuit alleged infringement of Augustine Medical's U.S. Patent Nos. 5,300,102 (the 102 patent), 5,324,320 (the 1320 patent), 5,405,371 (the 1371 patent), 4,572,188 (the 188 patent), and 5,350,417 (the 1417 patent) (collectively, the Augustine patents). The Augustine patents claim features of convective (or forced-air) thermal blankets. The

United States District Court for the District of Minnesota consolidated these separate suits for trial. Before trial, the district court granted summary judgment of invalidity of several asserted claims and non-infringement of others. At trial, a jury found infringement of the remaining claims under the doctrine of equivalents. Accordingly, the district court issued a permanent injunction prohibiting Mallinckrodt and Gaymar from making certain convective thermal blankets.

Because prosecution history estoppel limits application of the doctrine of equivalents to the asserted claims, this court reverses the district court's failure to grant judgment as a matter of law (JMOL) of non-infringement and vacates the entry of the permanent injunction. In addition, because the July 10, 1990 parent application does not provide sufficient support for claims 1, 3, 4, and 8 of the '371 patent, this court affirms the district court's decision that those claims are invalid under 35 U.S.C. § 102(b) (1994). This court also affirms the district court's summary judgment of non-infringement on the '188 patent. Finally, this court affirms the dismissal of Gaymar's invalidity claim on the '417 patent.

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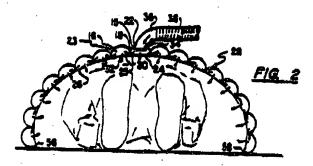
Convective thermal blankets inflate to direct warm (or cool) air onto a person. Surgeons often use these blankets during and after an operation to prevent or treat hypothermia caused by surgical conditions. Hypothermia results when a patient's body temperature drops below a cartain threshold. Surgery often presents the threat of hypothermia. A patient's body temperature may drop significantly during surgery because anesthesia prevents the patient's body from regulating its own temperature. Additionally, operating rooms — kept cool to accommodate the surgeon's working

conditions and to reduce the spread of germs - can chill patients. Moreover, surgery often calls for administration of cool intravenous fluids at a time when the patient's body cavity is open.

. A convective thermal blanket over the patient is thus necessary to prevent or treat hypothermia during and after surgery. Heated air from a warming unit inflates the blanket. Once inflated, the blanket directs heated air onto the patient through small holes (or "exit parts") in the undersurface of the blanket. With careful use, a convective blanket regulates patient temperature and prevents hypothermia.

The Augustine patents all stem from related applications and claim features in a particular convective thermal blanket design. Dr. Scott D. Augustine developed these features. The Augustine blanket design contains a series of hollow tubes with rounded upper surfaces and flattened lower surfaces joined in a parallel array. The geometric design of this structure allows it to "self-erect" when inflated and helps the blanket perform its function of warming the patient. According to the earliest of the Augustine patents, the '166 patent, the Augustine blanket has a "self-supporting structure having a generally rounded or elliptical cross-sectional shape which contacts the patient only at the tubes which are immediately adjacent the keystone tube." Col. 4, II. 12-16. When in use, air pressure from the exit ports raises these tubes slightly above the patient so that none of the tubes are in contact with the patient. This slight gap between the patient and the blanket facilitates "circulation . . . through those exit ports." Col. 4, II. 16-20. According to the specifications of the other three Augustine patents, the inflated blanket "erects itself into a Quonset hut-like structure." The 1102 patent, col. 3, II. 31-35, 49-50; the '320 patent, col. 3, ii. 11-12, 20-22; the '371 patent, col. 4, ii. 10, 17-19.

Figures in each of the Augustine patents illustrate this self-supporting, Quonset hut-like structure. Figure 2 of the '188 patent is representative.



Mallinckrodt and Gaymar manufacture and sell convective warming blankets to prevent or treat hypothermia. Mallinckrodt's and Gaymar's blankets (the accused blankets) are similar to each other in construction. The accused blankets feature an inflatable quilt-like structure. The accused blankets attach two sheets of the same amount of flexible, lightweight material around their periphery and at various spots along their surfaces. In operation, heated air flows onto a patient's body from holes in the undersurface of the accused blankets, but the blankets do not form a selfsupporting or Quonset hut-like structure. Instead, the accused blankets lie flat when inflated on a flat surface and rest substantially on a patient when in use. Mallinckrodt began selling its first model of convective warming blanket in June 1992. Gaymar began selling forced-air blankets in March 1992.

In October 1994, after issuance of the '102 and '320 patents in April and June 1994, Augustine Medical filed separate lawsuits against Mailinckrodt and Gaymar, initially alleging infringement of these two patents only. Augustine Medical later as well.

amended its original complaint to assert infringement of the '371, '188, and '417 patents

After consolidation of these lawsuits in the district court, Mallinckrodt and Gaymar moved for partial summary judgment, seeking a declaration of invalidity as to claims 1, 3, 4, and 8 of the '371 patent. The district court referred the case to a magistrate judge for recommendations. The magistrate judge concluded that the display of a prototype blanket triggered a § 102(b) on-sale bar. In reaching that conclusion, the magistrate judge found that the parent application Serial No. 07/550,757 (the '757 application), which was filed within one year after the display, did not sufficiently describe the invention of these claims of the '371 patent. Thus, the magistrate judge accorded thase claims the January 8, 1991 filing date of their continuation-in-part (CIP) application, not the June 10, 1990 filing date of the '757 application. With that finding in place, the magistrate judge recommended granting the summary judgment motion because Augustine Medical had "displayed, sold and distributed a written description of the device" embodying these claims more than one year before the effective filing date of the claims. The district court adopted the magistrate judge's Report and Recommendation and invalidated these claims.

In the fall of 1996, Augustine Medical signed a stipulation of dismissal with prejudice of all infringement claims arising out of the '417 patent. Augustine Medical further stipulated that none of Gaymar's products infringe any claim of the '417 patent. Based on these stipulations, the magistrate judge discerned no actual controversy amongst the parties concerning the '417 patent, thereby mooting Gaymar's claim that the '417 patent was invalid. The district court adopted this conclusion.

Before trial, both Gaymar and Mallinckrodt moved for partial summary judgment of non-infringement of the remaining claims of the '188, '102, '320, and '371 patents. In ... part, Gaymar and Mallinckrodt based these motions on prosecution history estoppel. With respect to the '188 patent, the district court granted summary judgment of noninfringement in favor of both Maillinckrodt and Gaymar. In this judgment, the district court followed the magistrate judge's recommendation. The magistrate judge had first construed the claims and found, based on that interpretation, that the accused blankets did not literally infringe the '188 patent as a matter of law. Then, based on the 'all elements rule," see Pennwalt Corp. v. Durand-Wavland, Inc., 833 F.2d 931, 935, 4 USFQ2d 1737, 1739-40 (Fed. Cir. 1987) (en banc); Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 50 U.S. 17, \_\_\_, 117 S. Ct. 1040, 1054, 41 USPQ2d 1865, 1871 (1997), the magistrate judge stated that application of the doctrine of equivalents to the claims of the '188 patent would render some of the claim elements meaningless. Specifically, because interpreting the claims as advocated by Augustine Medical would eliminate the claim limitations of "flattened," "substantially smooth," and "parallel array of hollow tubes," the district court found that the accused blankets did not infrings the '188 patent under the doctrine of equivalents.

With respect to the other patents, the magistrate judge detected a genuine issue of material fact relative to the "self-erecting" limitation. Specifically, the magistrate judge noted that "the Mallinckrodt blanket move[d] slightly away from the person underneath it and assume[d] a shape over the person when in operation. When considering the Gaymar blanket, the magistrate judge explained that "the blanket lift[ed] slightly away from the table as it [was] inflated." The magistrate judge also concluded

that two other elements of the Augustine Medical patent claims, a non-inflatable erectable foot drape and a non-inflatable extension at the head end, were present in Gaymar's blankets.

Based on the magistrate judge's Report and Recommendation of July 18, 1997, the district court granted the motions for summary judgment of non-infringement with respect to the '188 patent, but denied the motions with respect to the '102, '320, and '371 patents (the remaining patents in suit). The district court identified the same issue of material fact regarding whether Gaymar's and Mallinckrodt's blankets literally or equivalently self-erect. Neither the magistrate judge nor the district court substantively addressed the prosecution history estoppel defense.

The district court ordered a seriatim trial on the remaining patents in suit, with the first phase to determine infringement and willfulness and the second phase to determine damages, if necessary. At trial, the most contested issue between the parties was the meaning of the term "self-erecting." The district court determined that this limitation is either explicitly or implicitly present in each of the disputed patent claims of the '102, '320, and '371 patents. The magistrate judge had defined "self-erecting" to mean that the "blanket forms a structure around the patient when it is inflated." Rather than adopt the magistrate judge's interpretation, however, the district court, in its instructions to the jury, interpreted the term to require "that the device form a curved or arched structure which stands off the patient."

<sup>3</sup>After trial, the jury returned a verdict finding that Mallinckrodt and Gaymar had not literally infringed any of the patent claims, but had infringed all of the asserted claims under the doctrine of equivalents. Based on this verdict, the district court

entered a permanent injunction prohibiting both Gaymar and Mallinckrodt from making, using, or selling certain forced-air warming blanksts.

Mallinckrodt and Gaymar both appeal the entry of the permanent injunction. Gaymar and Mallinckrodt also each sought judgment as a matter of law or a new trial under Fed. R. Civ. P. 50(b) and 69. Because these post-trial motions remained pending before the district court at the time of the appeal, the parties appealed under 28 U.S.C. § 1292(a)(1) and (c)(1) (1994). The district court later denied the parties' post-trial motions. Gaymar also appeals the dismissal of its claim of invalidity with respect to the '417 patent. Augustine Medical cross-appeals the grant of summary judgment of invalidity with respect to claims 1, 3, 4, and 8 of the '371 patent and challenges the district court's construction of the "self-erecting" limitation.

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Because a correct Infringement analysis requires a correct claim interpretation, see Markman v. Westview instruments, Inc., 52 F.3d 967, 976, 34 USPQ2d 1321, 1328 (Fed. Cir. 1995) (en banc), affd, 517 U.S. 370 (1996); Key Manufacturing Group, Inc. v. Microdot, Inc., 925 F.2d 1444, 1448, 17 USPQ2d 1806, 1809 (Fed. Cir. 1991); SmithKlina, Diagnostics, Inc. v. Helena Laboratories Corp., 859 F.2d 878, 885, 8 USPQ2d 1468, 1474 (Fed. Cir. 1988), this court begins its review of the jury's verdict with a review of the district court's claim interpretation. This court reviews the district court's claim construction without deference. See Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454-56, 46 USPQ2d 1169, 1172-75 (Fed. Cir. 1998) (en banc); Markman, 52 F.3d at 979-81.

The primary issue of claim interpretation is the meaning of "self-erecting." Discharging its duty to give meaning to the claims, the district court instructed the jury that the term "self-erecting" required "that the device form a curved or arched structure which stands off the patient." Augustine Medical argues that "self-erecting" requires only that the blanket form an "environment" about the patient in which warm air can circulate. Under its proposed claim interpretation, Augustine Medical argues that the accused blankets literally "self-erect" because they create an environment of circulating warm air about a patient.

This court finds no support for Augustine Medical's claim construction. The patents themselves define what the claims mean by "self-erecting." As noted above, the '188 patent describes its structure as "a self-supporting structure having a generally rounded or elliptical cross-sectional shape which contacts the patient only at the tubes which are immediately adjacent the keystone tube." Col. 4, il. 12-16. The other patents all explain that a blanket which "self-erects" "erects itself into a Quonset hut-like structure" when inflated. The '102 patent, col. 3, II. 31-35; the '320 patent, col. 3, II. 11-12, 20-22; the '371 patent, col. 4, II. 10, 17-19. Thus, the district court correctly construed the term "self-erecting" to require that the accused blankets "form a curved or arched structure which stands off the patient." Following this interpretation, the jury found that the accused blankets did not literally infringe. The jury did, however, find infringement under the doctrine of equivalents.

As noted earlier, the accused blankets are made of a flexible, lightweight material which rests substantially on a patient when in use. When inflated, air exits through ports in the bottom of the blanket and passes over the patient's body. The

evidence suggests that the accused blankets raise slightly away from the patient's body in the areas adjacent to the exit ports. The magistrate judge noted that "while viewing the inflation of the Mailinckrodt device in court and on video, ... the Mailinckrodt blanket move[d] slightly away from the person underneath it and assume[d] a shape over the person." When considering the Gaymar blanket, the magistrate judge explained that "the blanket lift[ed] slightly away from the table as it [was] inflated." Because the accused blankets assume the contours of, and rise slightly above, the patient's body, Augustine Medical contends that there is substantial evidence to support the jury's finding that the accused blankets at least contain an equivalent to the claimed "self-erecting" limitation.

In reviewing challenges to the sufficiency of the evidence supporting a jury verdict of infringement under the doctrine of equivalents, this court determines whether substantial evidence supports the jury's findings. See Texas Instruments, Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1567, 39 USPQ2d 1492, 1499 (Fed. Cir. 1996). Although the doctrine of equivalents may occasionally extend the reach of a claim beyond its literal scope, several principles strictly limit application of the doctrine. For instance, the "all elements" rule provides the analytical framework for conducting an infringement analysis under the doctrine of equivalents that avoids undue expansion of a patent's claims. See Litton Sys. Inc. v. Honeywell, Inc., 140 F.3d 1449, 1464, 48 USPQ2d 1321, 1324 (Fed. Cir. 1998). Prosecution history estoppel also limits undue expansion of a claim's scope through the doctrine of equivalents. See Warner-Jenkinson, 117 S. Ct. at 1047, 1049-51. Specifically, prosecution history estoppel prevents a patentee from recapturing subject matter surrendered during prosecution of

the patent. <u>See Id.</u>; <u>Southwall Techs., Inc. v. Cardinal IG Co.</u>, 54 F.3d 1570, 1579-81, 34 USPO2d 1673, 1679 (Fed. Cir. 1995). The application of prosecution history estoppel is a question of law which this court decides without deference to the district court. <u>See Cybor</u>, 138 F.3d at 1460.

To determine the scope of estoppel, this court examines objectively whether a competitor would reasonably conclude that an applicant's prosecution conduct had surrendered the disputed subject matter. See Cybor, 138 F.3d at 1457 ("The relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter."). "Either amendments or arguments made by an applicant may be the basis for this conclusion." Litton, 140 F.3d at 1462.

Although not dispositive, the prior art may aid in determining the scope of an estoppel. "[A] patentee is estopped from recovering through equivalency that which was desired unpatentable in view of the prior art." Pall Corp. v. Micron Separations. Inc., 66 F.3d 1211, 1219, 36 USPO2d 1225, 1230 (Fed. Cir. 1995). After adding a claim limitation during prosecution to overcome prior art, the applicant cannot later assert that the distinguished feature of the prior art is equivalent to the added limitation. See Litton, 140 F.3d at 1482. Similarly, the patentee may not assert coverage of a "trivial" variation of the distinguished prior art feature as an equivalent. See id. "If sufficient to evince a clear and unmistakable surrender of subject matter," arguments made during prosecution "may [also] estop an applicant from recapturing that surrendered matter under the doctrine of equivalents." Id. at 1458. This court, therefore, must consider whether the prosecution history of the Augustine patents

precludes Augustine Medical from asserting coverage of the accused blankets under the doctrine of equivalents.

The specifications and file histories of the Augustine patents contain clear representations that not only define the acope of the "self-erecting" limitation, but also show that the claims cover only convective warming blankets which are "self-erecting." The specification of the '188 patent references two primary categories of prior art thermal blankets, conductive and convective. The '188 patent criticizes conductive prior art blankets because they touch the patient. The '188 patent explains that conductive blankets provide little warmth beyond the areas in direct contact with the blanket. Col. 1, II. 23-30. Outside these local areas of warmth in direct contact with the blanket, conductive blankets transfer only minimal warmth by heat radiation. Col. 1, II. 33-38. This combination of conductive and radiative heating results in non-uniform heat transfer. The parts of the patient's body in direct contact with the blanket have a significantly higher temperature than the average body temperature while the other parts of the patient's body have a significantly lower temperature. Col. 1, II. 25-30. Additionally, the '188 specification explains, conductive blankets carry a significant risk of burning the patient's skin at points of direct contact. Col. 1, II. 30-33.

The '188 patent also criticizes convective prior art blankets. In these blankets, as in the '188 claimed invention itself, a heat transfer medium such as air circulates to provide temperature control. Col. 1, II. 37-47. Convective thermal blankets are not new. The convective prior art referenced in the '188 patent includes U.S. Patent No. 2,093,634 (Gaugler) which issued in 1937. In fact, Mallinckrodt and Gayrnar both claim to have based their blanket design on expired U.S. Patent No. 2,512,559 (Williams).

U.S. Patent Nos. 2,110,022 (Kliesrath) and 4,660,388 (Greene) also disclose certain convective thermal blankets.

The '188 patent specifically discusses the disadvantages of the Kliesrath convective cover. According to the '188 patent, the Kliesrath convective blanket circulates air "inside a flexible bag which has a top insulating layer and a bottom heat conducting layer which contacts the patient." Col. 1, II. 39-42. According to Kliesrath, the "heat conducting layer" is "a relatively thin sheet of cotton, linen, silk or the like," that allows passage of warm air to transfer heat onto the patient. Kliesrath, col. 2, II. 4-5, 21-27; col. 1, II. 31-35. The '188 patent criticizes the structure of the Kliesrath blanket as "unnecessarily heavy and rigid." Col. 1, II. 42-43. Specifically, the '188 patent complains that "the weight of the blanket can press its inner surface against the covered patient and block a number of the exit ports, thereby reducing the total body area over which the air is circulated." Col. 1, II. 43-47.

As a solution to the problems of both the conductive and convective prior art blankets, the '188 patent introduces "a lightweight, flexible, inflatable casing [which inflates] into a self-supporting structure which encloses the patient." Cot. 1, II. 55-68. The specification of the '188 patent thereby invokes its self-erecting structure to distinguish the invention from both convective and conductive prior art thermal blankets. Col. 1, II. 63-66; col. 2, II. 12-18.

The '102 patent, dated April 1994, incorporated the description of the prior art in the '188 patent by reference. Col. 1, II. 16-19. The '102 patent additionally describes the invention of the '188 patent as "a self-erecting, inflatable sirflow cover." Col. 1, II. 19-20. The '102 patent proceeds to describe the operation of the '188 claimed

invention: "When inflated, the cover self-erects about a patient, thereby creating an ambient environment about the patient." The '102 patent specification also expressly defines the term "thermal blanket," contained in each of its claims, with reference to the "self-erecting" feature: "the term 'thermal blanket' is meant to invoke a self-erecting, inflatable structure for delivering a thermally controlled inflating medium to the interior of the structure created when the thermal blanket is inflated." Col. 3, II. 30-34.

After the '102 patent issued, the '320 and '371 patents issued in June 1994 and in April 1995, respectively. Like the '102 patent, the '320 and '371 patents also incorporate the disclosure of the '188 patent by reference and describe the invention as 'a self-erecting, inflatable airflow cover." The '320 patent, col. 1, il. 16-17; the '371 patent, col. 1, II. 19-20. The Augustine patents therefore identify the "self-erecting" structure as the primary advantage over the prior art. This distinction appears even more prominently in the file histories of the Augustine patents.

The prosecution histories of the Augustine patents show that the applicant expressly surrendered coverage of any forced-air blanket other than a "self-erecting" convective thermal blanket which stands off of a patient when in operation. During prosecution of application No. 07/227,189 (the '189 application), a parent application to later applications resulting in the '102, '320 and '371 patents, Augustine Medical canceled or amended all of the original claims in favor of new claims containing the "self-erecting" limitation. Augustine Medical made these amendments in response to the examiner's rejections over the prior art. The prosecution history explains:

All of the new claims are drawn to a self-erecting, inflatable thermal blanket which bathes a person in a thermally controlled inflating medium. Such a thermal blanket is one which, when inflated, erects about a

person, standing off of the person to exhaust the inflating medium which thereby bathes the person in the medium.

During the prosecution of the '189 application, Augustine Medical also presented arguments to overcome the examiner's reliance on the conductive prior art blanket  $\sim$ references. Specifically, Augustine Medical argued:

The airflow cover and the convective thermal blanket, when inflated, stand off a patient. This is vital to the blanket's operation, since contact with the patient would block passage of the inflating medium through the occluded apertures in the undersurface and would prevent the blanket from bathing the patient in an inflating medium.

Because the prosecution history of a parent application may limit the scope of a later application using the same claim term, see Jonsson v. Stanley Works, 903 F.2d 812, 818, 14 USPQ2d 1863, 1870 (Fed. Cir. 1990), these claim amendments and arguments restrict the scope of the claims in each of the later issued patents containing the "selferecting" limitation.

During prosecution of the application leading to the '102 patent, Augustine Medical again focused on the unique "self-erecting" structure of its blanket to distinguish the Greene and Kliesrath convective prior art. Augustine Medical represented that its "air flow cover consists entirely and solely of an inflatable tubular structure which, when inflated by an inflating medium, erects about a person." According to the applicant, the structure of the claimed invention differs from Greene because it "permits the thermal blanket to assume the shape of a curved surface which curls downwardly toward its edges from its center and forms a quonset-type structure." Still a further reference in the '102 patent file history argues that "the thermal blanket disclosed and claimed in this application is different from the device disclosed by Greene because it self-erects." Augustine Medical therefore clearly asserted that "the

air flow cover of the '188 [patent] and thermal blanket of this application are significantly different from the covers of Greene and Kilesrath' because of this self-erecting structure.

Augustine Medical made representations nearly Identical to those discussed with reference to the '102 patent to overcome the examiner's reliance on Greene and Kilesrath during the prosecution of the application leading to the '371 patent. The prosecution history of the '320 patent also contains limiting representations. Specifically, Augustine Medical distinguished over the prior art by stating that the invention covers the 'class of convective thermal blankets, or airflow covers ... which are inflatable and which self-erect when inflated. When inflated, these blankets cool or warm a patient enclosed in the self-erected structure."

In sum, during prosecution of the '102, '320, and '371 patents, Augustine Medical amended the claims to expressly include a "self-erecting" limitation and made clear representations of the scope of that limitation to overcome the prior art. Augustine Medical therefore surrendered during prosecution the coverage it now seeks to reclaim via the doctrine of equivalents. The record of the administrative proceedings before the PTO precludes coverage of allegedly equivalent blankets which rest on a patient and do not inflate themselves into a self-supporting Quonaet hut-like structure. The district court therefore erred by declining to grant Gaymar's and Maillinckrodt's motion for JMOL and by entering a permanent injunction against them. Because this court determines that application of prosecution history estoppel bars Augustine Medical from extending the scope of its patent claims to cover the accused devices, this court need not address

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whether Augustine Medical's proof on equivalence was sufficient to support the jury's verdict.

Relying on this court's early statements that pioneering inventions deserve a broader range of equivalents, see, e.g., Perkin-Elmer Corp. v. Westinghouse Elec. Corp., 822 F.2d 1528, 1532, 3 USPQ2d 1321, 1323 (Fed. Cir. 1987); Thomas & Betts Corp. v. Litton Sys., Inc., 720 F.2d 1572, 1579, 220 USPQ 1, 6 (Fed. Cir. 1983), Augustine Medical appears to argue that because its patents "revolutionized the treatment of surgical patients" they deserve broader protection. At the outset, this court notes that no objective legal test separates ploneers from non-pioneers. See, e.g., Sun Studs, Inc. v. ATA Equip. Leasing Inc., 872 F.2d 978, 987, 10 USPQ2d 1338, 1346 (Fed. Cir. 1989) (stating that pioneer status depends on all factual circumstances). Furthermore, it is impossible for this court or the PTO to predict the future of any given technology and thereby determine the likelihood that an invention will open vast new vistas of innovation. The peripheral daiming system itself, however, makes the best distinction between pioneers and non-pioneers. Ploneers enjoy the benefits of their contribution to the art in the form of broader claims. Without extensive prior art to confine and cabin their claims, pioneers acquire broader claims than non-pioneers who must craft narrow claims to evade the strictures of a crowded art field. Thus, claim scope itself generally supplies broader exclusive entitlements to the pioneer. Moreover, a pioneer generally need not fear traditional limits on the application of the doctrine of aquivalents such as prior art or prosecution history estoppel (because amendments or arguments to overcome the prior art are generally unnecessary in true pioneer

applications) - a concept different from Augustine Medical's plea for enhancing the scope of equivalents.

Augustine Medical notes that the extensive convective thermal blanket prior art (with the possible exception of Kliesrath which discussed treatment of diseases) did not explain the use of convective warming blankets for the prevention or treatment of hypothermia. To support its claim for a broader scope of equivalents, Augustine Medical points out that before Dr. Augustine's invention in 1986, doctors had used a variety of ineffective methods to treat hypothermia - such as infra-red heat lamps, hot water mattresses, heat/moisture exchangers, and cotton blankets. Augustine Medical therefore argues that its invention "pioneered" the commercialization of convective warming" for the treatment and prevention of hypothermia.

None of Augustine Medical's patents, however, claim a method of preventing and treating hypothermia. Rather, the Augustine patents contain only the apparatus claims discussed above. Even if a court could determine that Dr. Augustine had pioneered a method of treatment, that work cannot expand the coverage of apparatus claims to cover every apparatus used for the same purpose. In sum, although Augustine Medical's apparatus claims give patent protection covering "all uses" for the claimed apparatus. Augustine Medical cannot use the patent laws to proscribe use of another non-infringing apparatus to perform a method which is not daimed.

With respect to Augustine Medical's cross-appeals, this court first addresses the district court's grant of summary judgment of invalidity with respect to claims 1, 3, 4, and 8 of the '371 patent. This court reviews without deference the requirements for

summary judgment. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247 (1986). If any genuine issue of material fact remains in dispute, summary judgment is inappropriate. See Fed. R. Civ. P. 58(c). In reviewing a grant of summary judgment, this court resolves all factual inferences and doubts in favor of the non-moving party.

See Anderson, 477 U.S. at 256; Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1307, 46 USPQ2d 1752, 1755 (Fed. Cir. 1998).

This court therefore examines the record for genuine factual issues with regard to whether claims 1, 3, 4, and 8 are entitled to the July 1990 priority date of the '371 patent's parent application, the '757 application. If these claims deserve the July 1990 priority date, the display in October 1989 of two prototype blankets occurred after the critical date and could not erect a § 102(b) bar.

The '371 patent issued from an application continued in part from the '757 application. A CIP application contains subject matter from a prior application and may also contain additional matter not disclosed in the prior application. See Waldemar Link v. Osteonics Corp., 32 F.3d 556, 558, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994). Different claims of such an application may therefore receive different effective filing dates. See id. Subject matter that arises for the first time in the CIP application does not receive the benefit of the filing date of the parent application. See id. Thus, the decision on the proper priority date – the parent application date or the CIP application date – for subject matter claimed in a CIP application depends on when that subject matter first appeared in the patent disclosures. To decide this question, a court must examine whether the "disclosure of the application relied upon reasonably convey[s] to the artisan that the inventor had possession at that time of the later claimed subject

matter." Id. (quoting Wang Lab., Inc. v. Toshiba Corp., 993 F.2d 858, 865, 26 USPQ2d 1766, 1774 (Fed. Cir. 1993)). This is a question of fact. See id.

The magistrate judge found that the '757 application does not disclose the subject matter claimed in claims 1, 3, 4, and 8 of the '371 patent. Therefore, the magistrate judge denied these claims the '757 application's July 10, 1990 filing date. These claims each claim a convective warming blanket which covers only a portion of a patient's body. Although Augustine Medical points to passages from the '7.57 parent application that it asserts supports the claimed subject matter, these passages, in fact, do not at all relate to the claimed subject matter.

With respect to the lower body blanket in claim 1, for example, Augustine Medical refers to statements by its expert witness that language in the specification discussing drawing the blanket "up to the chin area" supports the claimed subject matter. Specifically, Augustine Medical conclusively asserts that this language, in conjunction with the understanding that care sites must be kept visible and clean. supports a blanket covering any other limited body area below the chin, including the lower body blanket of claim 1. To the contrary, this language does not suggest, let alone disclose, a lower body blanket. Rather, the only discussion of care sites relates to those in the head and neck region. Nowhere is there a suggestion, nor is it inherent, that similar blankets may be constructed for the treatment of other care sites.

Similarly, with respect to claims 3, 4, and 8, the passages pointed to as providing support for the claimed subject matter are insufficient. Claim 3 is dependent on claim 1 and is therefore unsupported for the same reasons as claim 1. Claim 4 covers a blanket which is positioned across the arms and chest of a patient's body. Augustine

Medical again points to the statement in the parent application that the blanket could be drawn up to the patient's chin and argues that it is therefore inherent that its blanket "could be positioned in many ways" including transverse disposition of the blanket over a patient's arms and chest. Augustine Medical's conclusory statements are again wholly insufficient to explain how one of skill in the art would find support for the invention in claim 4 from this language of the '757 application. Like claim 4, claim 8 is also directed toward a transverse blanket which covers a patient's arms and chest and is similarly unsupported by the '757 application. For these reasons, no reasonable jury could have found support for claims 1, 3, 4, or 8 of the '371 patent in the '757 application. Accordingly, there is no genuine issue of material fact in dispute and the district court's grant of summary judgment of invalidity with respect thereto was appropriate.

IV.

Augustine Medical's cross-appeal further challenges the district court's grant of summary judgment of non-infringement with respect to the '188 patent. Claim 1 is the only disputed independent claim of the '188 patent. Claim 1 recites, in part, "an inflatable cover housing including a plurality of inflatable hollow tubes, each tube having a rounded upper portion and a flattened lower portion, joined in a substantially parallel array to form a substantially smooth lower cover surface."

After initially recommending against a grant of summary judgment, on March 15, 1996, the magistrate judge revisited that recommendation on July 18, 1997. In this later recommendation, the magistrate judge concluded that the accused blankets did not infringe the '188 patent claims literally or under the doctrine of equivalents. Specifically, the magistrate judge concluded that the accused blankets did not literally contain tubes, a parallel array of chambers, a flattened lower cover surface, or a substantially smooth lower cover surface. The magistrate judge further concluded that the accused blankets lacked equivalents of these limitations.

Although, under the doctrine of equivalents, an element or limitation of the claim is not required to be literally present in the accused device, the accused device must still contain an equivalent of that element or limitation. See Warner Jenkinson, 117 S. Ct. at 1054. In this case, the "flattened lower portion" is completely absent in the accused blankets. The "flattened lower portion" is not literally present because the accused blankets have a quitted lower surface nearly identical to their upper surface. The accused blankets also lack any feature equivalent to the "flattened lower portion."

To infringe under the doctrine of equivalents, the accused blankets must contain features which are insubstantially different than the claim elements. Insubstantial differences may be found where a structure performs substantially the same function in substantially the same way to achieve substantially the same result as the claim element. As explained in the specification, the "flattened lower portion" claim element functions together with the "rounded upper portion" to create a structure that avoids contact with the patient.

When the cover is placed over the patient and inflated, the pressure of one tube against another is collected at the edges of the cover which causes the edges to curl down around the patient toward the [bed] surface. . . [T]he inflation of the tubes provides the cover with a self-supporting structure having a generally rounded or elliptical cross-sectional shape which contacts the patient only at the tubes which are immediately adjacent the keystone tube.

'188 patent, coi. 4. II. 7-16. The inclusion of both of these elements is necessary to have a "self-erecting structure" in which the patient can be bathed in the temperature controlled medium. Based on the undisputed facts, no reasonable jury could conclude that there are features of the accused blankets which are insubstantially different than the "flattened lower portion" limitation. The record shows that the accused blankets have nearly identical, quilted upper and lower surfaces and that the blankets rest on and maintain significant contact with the patient when inflated. Augustine Medical is unable to point to and we are unable to identify any features of the accused blankets which could function to create a "self-supporting structure" that avoids contact with the patient. Therefore, because the undisputed facts show that the accused blankets do not literally or equivalently contain every limitation of the '188 patent claims, there can be no infringement. Accordingly, the district court appropriately granted summary judgment of non-infringement with respect to the '188 patent.

Finally, with respect to the district court's dismissal of Gaymar's claim of invalidity regarding the '417 patent, Augustine Medical dismissed with prejudice all claims against Gaymar related to the '417 patent and stipulated that none of Gaymar's products infringed the '417 patent. This court agrees with the district court that this stipulation and dismissal of claims with prejudice eliminated any potential case or controversy and thereby mooted Gaymar's claim of invalidity. This court finds Gaymar's assertions to the contrary unpersuasive.

VI.

Because prosecution history estoppel bars Augustine Medical from recapturing convective thermal blankets which are not "self-erecting," this court reverses the imposition of the injunction against Gaymar and Mallinckrodt as well as the district court's refusal to grant JMOL of non-infringement. However, because this court concludes that no reasonable jury could find sufficient support for claims 1, 3, 4, and 8 of the '371 patent in the '757 application, this court affirms the district court's grant of summary judgment that these claims are invalid under § 102(b). Furthermore, because the district court did not err in construing the elements of the '188 patent claims or in applying the "all elements" rule of the doctrine of equivalents, this court affirms the district court's grant of summary judgment of non-infringement with respect to the '188 patent. Finally, because the district court appropriately determined that Gaymar's claim of patent invalidity with respect to the '417 was moot in light of the stipulations of fact entered by Augustine Medical, this court affirms that decision.

COSTS

Each party shall bear its own costs.

AFFIRMED-IN-PART, REVERSED-IN-PART

#### COMBINED PETITION FOR REHEARING AND SUGGESTION FOR REHEARING IN BANC OF PLAINTIFF-CROSS-APPELLANT AUGUSTINE MEDICAL, INC.

#### UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

98-1001, -1002, -1054, -1244, -1266

AUGUSTINE MEDICAL, INC.,

Plaintiff-Cross-Appellant,

GAYMAR INDUSTRIES, INC. and MEDISEARCH PR, INC.,

Defendants-Appellants,

and

MALLINCKRODT GROUP, INC. and MALLINCKRODT MEDICAL, INC.,

Defendants-Appellants.

Appeal from the United States District Court for the District of Minnesota in 94-CV-875, 94-CV-888, 96-CV-347 and 96-CV-1145, Judge James M. Rosenbaum

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June 21, 1999

#### **CERTIFICATE OF INTEREST**

Pursuant to Rule 47.4 of the Rules of this Court, Plaintiff-Cross-Appellant Augustine Medical, Inc. submits this Certificate of Interest as follows:

- 1. The full name of the party represented by counsel listed below is:

  Augustine Medical, Inc.
  - 2. Augustine Medical, Inc. is the real party in interest in this case.
- 3. Augustine Medical, Inc. has no parent companies, subsidiaries or affiliates that have issued shares to the public.
- 4. The names of all law firms and the partners or associates that have appeared for the parties now represented by the undersigned in the trial or who are expected to appear in this Court are:

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5. The names of attorneys that have appeared for the parties now represented by the undersigned who are no longer associated and/or affiliated with the undersigned firm are:

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### TABLE OF CONTENTS

	Page #
CEF	RTIFICATE OF INTERESTi
TAE	LE OF CONTENTSiii
	LE OF AUTHORITIES v
STA	TEMENT OF COUNSELvi
POI	NTS OF LAW OR FACT 1
I.	THE COURT DID NOT CONSIDER, AND ITS DECISION NOW CONFLICTS WITH, THE DIRECTLY APPLICABLE PRECEDENT OF COMMERCE COMMUNICATIONS INC. V. HARRIS CORP. THAT THE BURDEN IS ON THE APPELLANT TO SHOW EITHER THAT THE JURY COULD NOT REASONABLY FIND A PARTICULAR LIMITATION LITERALLY OR THAT THERE WAS NOT SUFFICIENT EVIDENCE ON EQUIVALENTS AS TO ANY ELEMENT
	EXCEPTIONAL IMPORTANCE, NAMELY WHETHER THE JURY SHOULD BE AFFORDED ANY DEFERENCE AS TO THE FACTUAL INQUIRY OF WHAT A COMPETITOR WOULD REASONABLY CONCLUDE IN DETERMINING THE SCOPE OF ESTOPPEL
FAC	TS RELEVANT TO BOTH PETITION AND SUGGESTION 1
I.	TRIAL COURT PROCEEDINGS 1
II.	APPEAL 3
ARG	UMENT PETITION FOR REHEARING 5
I.	THIS COURT'S DECISION IN COMMERCE COMMUNICATIONS INC. V. HARRIS CORP. IS DIRECTLY ON POINT AND MUST BE CONSIDERED

	<i>A</i> .	Neither Gaymar Nor Mallinckrodt Satisfied Its Burden Under Comark	6
	В.	The Record Demonstrates That The Jury Could Have Found Literal Infringement Of The "Self-Erecting" Limitation	
	С.	The Literal Scope Of "Self-Erecting" Was Not And Should Not Be Limited To The Scope Of Dependent Claims Directed To A "Self-Supporting" Blanket	7
	D.	A Rehearing Is Necessary To Consider The Question Of Literal Infringement Of The Claim Limitation "Self- Erecting" Based On The Record	10
AR	GUME	NT - SUGGESTION FOR REHEARING IN BANC	10
I.	COL V. H. THE PAR	PANEL'S DECISION IS IN CONFLICT WITH THIS JIRT'S DECISION IN COMARK COMMUNICATIONS INC. ARRIS CORP. REGARDING JURY VERDICTS WHERE VERDICT FORM DOES NOT STATE WHETHER A TICULAR LIMITATION WAS FOUND LITERALLY EQUIVALENTLY.	10
II.	EST	ETHER THE SCOPE OF PROSECUTION HISTORY OPPEL SHOULD BE DECIDED AS A MATTER OF OR OF FACT IS A QUESTION OF EXCEPTIONAL	
	IMP	ORTANCE	11
	А.	The Jury's Verdict Included The Jury's Consideration Of Estoppel And It Cannot Be Set Aside Without Offending The Seventh Amendment To The United States Constitution	12
CON	NCLUS	SION	14
ADI	ENDU	J <b>M</b>	

#### TABLE OF AUTHORITIES

#### **CASES**

Comark Communications Inc. v. Harris Corp., 156 F.3d 1182,	`
48 U.S.P.Q. 2d 1001 (Fed. Cir. 1998)	vi,1,
	4,5
	6,10
	11
DMI, Inc. v. Deere &Co., 802 F.2d 421 (Fed. Cir. 1986)	13
Haynes International Inc. v. Jessop Steel Co., 8 F.3d 1573,	
28 U.S.P.Q. 2d 1652 (Fed. Cir. 1993), on reh'g, 15 F.3d 1076,	
29 U.S.P.Q. 2d 1958 (Fed. Cir. 1994)	12
Markman v. Westview Instruments, Inc., 116 S. Ct. 1384 (1996)	12
Modine Mfg. Co. v. U.S. Intern. Trade Com'n, 75 F.3d 1545	
(Fed. Cir. 1996), cert. denied, 116 S. Ct. 1523 (1996)	. 12,13
Paltex Corp. v. Mossinghoff, 758 F.2d 594 (Fed. Cir. 1985)	12
Transmatic, Inc. v. Gulton Industrial, Inc., 53 F.3d 1270,	
35 U.S.P.Q. 2d 1035 (Fed. Cir. 1995)	8

#### STATEMENT OF COUNSEL

Based on my reasoned and studied professional judgment, I believe the panel decision is contrary to the following precedent of this Court: Comark Communications Inc. v. Harris Corp., 156 F.3d 1182, 48 U.S.P.Q.2d 1001 (Fed. Cir. 1998).

Based on my reasoned and studied professional judgment, I believe this appeal requires answer to one or more precedent-setting questions of exceptional importance: Whether the right to trial by jury granted in the Seventh Amendment to the Constitution of the United States is offended by the failure to give deference to the jury's determination of the scope of estoppel a reasonable competitor could rely on from a reading of the claims, specification and file history?

ATTORNEY OF RECORD FOR PLAINTIFF-CROSS-APPELLANT AUGUSTINE MEDICAL, INC.

#### POINTS OF LAW OR FACT

- I. THE COURT DID NOT CONSIDER, AND ITS DECISION NOW CONFLICTS WITH, THE DIRECTLY APPLICABLE PRECEDENT OF COMARK COMMUNICATIONS INC. V. HARRIS CORP. THAT THE BURDEN IS ON THE APPELLANT TO SHOW EITHER THAT THE JURY COULD NOT REASONABLY FIND A PARTICULAR LIMITATION LITERALLY OR THAT THERE WAS NOT SUFFICIENT EVIDENCE ON EQUIVALENTS AS TO ANY ELEMENT.
- II. THIS PROCEEDING INVOLVES A QUESTION OF EXCEPTIONAL IMPORTANCE, NAMELY WHETHER THE JURY SHOULD BE AFFORDED ANY DEFERENCE AS TO THE FACTUAL INQUIRY OF WHAT A COMPETITOR WOULD REASONABLY CONCLUDE IN DETERMINING THE SCOPE OF ESTOPPEL.

#### FACTS RELEVANT TO BOTH PETITION AND SUGGESTION

#### I. TRIAL COURT PROCEEDINGS.

Appellee-Cross Appellant Augustine Medical, Inc. ("Augustine") brought an action for infringement of four patents directed to convective warming blankets against Appellants Gaymar Industries, Inc. ("Gaymar") and Mallinckrodt Group, Inc. ("Mallinckrodt"). Addendum ("Add.") at 3. The patents in suit are U.S. Patent Nos. 5,300,102 ("the '102 patent"), 5,324,320 ("the '320 patent"), 5,405,371 ("the '371 patent") and 4,572,188 ("the '188 patent"). Add. at 3. The patented convective warming blankets are used before, during and after surgery to control a pateint's body temperature by bathing the patient in circulating warm air. Add. at 4. At trial, all elements of Augustine's claims were disputed and

submitted to the jury including "self-erecting," "discontinuous seams" attaching the upper and lower sheets of the blankets, and "chambers."

The trial court instructed the jury that "self-erecting" means the inflated blanket forms a "curved or arched structure which stands off the patient." Add. at 9; JA04184 II. 4-6. The trial court had denied Appellants' motions for summary judgment with respect to the "self-erecting" limitation, ruling it is a jury question of whether the accused blankets <u>literally</u> self-erect. Add. at 9. Augustine put on a case of literal and equivalent infringement. Appellants conceded at trial that a "self-erecting" blanket can contact the patient at some points, but argued that the accused blankets exhibited too much contact to meet the self-erecting limitation literally. Thus, a substantial fact question for the jury was whether, in operation, the accused blankets "stand off" the patient.

At Appellants' request, the jury was instructed to consider the scope of any prosecution history estoppel. JA04186-04187 ll. 20-5. The jury returned a general verdict of infringement of numerous claims of the '102, '320 and '371 patents under the doctrine of equivalents. Add. at 11. The verdict form did not specify which elements were found literally and which were found equivalently. JA00018-00028A.

#### II. APPEAL.

Gaymar and Mallinckrodt appealed, arguing prosecution history estoppel as to the claim element "self-erecting" and challenging the sufficiency of the evidence of equivalence as to all elements. Mallinckrodt Brief at pp. 32-39, 42-49; Gaymar Brief at 25-45. Appellants did not appeal the trial court's definition of "self-erecting," namely, "forms a curved or arched structure which stands off the patient." Add. at 9.

This Court quoted with approval the trial court's claim definition "forms a curved or arched structure that stands off the patient." Add. at 11. This Court observed that the magistrate judge noted that "the Mallinckrodt blanket move[d] slightly away from the person underneath it and assume[d] a shape over the person" when in operation, and the Gaymar "blanket lift[ed] slightly away from the table as it [was] inflated." Add. at 8. Finally, this Court noted that the trial court found an issue of fact which was submitted to the jury as to whether the accused blankets self-erect literally. Add. at 9.

Although many elements were disputed and there was no special verdict form specifying how each element was met, this Court implicitly concluded that the jury did not find the "self-erecting" limitation literally and ruled that prosecution history estoppel precluded a finding of "self-erecting" by equivalents.

Add. at 4 & 11. It appears that this Court further construed "self-erecting" to include the additional limitation "self-supporting," which appears in dependent claim five of the '188 patent, and ruled that the accused blankets are not literally. "self-supporting" as a matter of law. Add. at 11.

The Detailed Description Of The Preferred Embodiments in the '188 patent describes a "self-supporting" blanket as one where "the edges curl down around the patient" such that the blanket "contacts the patient only at the tubes which are immediately adjacent to keystone tube." JA04302 col. 4 ll. 7-16. The specifications of the other patents-in-suit note that "tubes are preferred since they impart shape and strength to the erected bathing structure; other inflatable structures are contemplated, however." (Emphasis added.) JA04430 col. 4 ll. 63-66; JA04631 col. 4 ll. 33-36; JA05038 col. 5 ll. 31-34.

This Court did not explicitly address literal claim scope, nor did it address the open question of literal infringement. Furthermore, this Court chose to disregard its recent precedent in *Comark Communications Inc. v. Harris Corp.*, 156 F.3d 1182, 1187, 48 U.S.P.Q.2d 1001, 1005 (Fed. Cir. 1998) pertaining to jury verdicts under the doctrine of equivalents where no special interrogatory is used to show which elements are found equivalently and which are found literally.

Consequently, Augustine has filed this combined petition for rehearing and suggestion for rehearing in banc.

#### **ARGUMENT -- PETITION FOR REHEARING**

I. THIS COURT'S DECISION IN COMARK COMMUNICATIONS INC.

V. HARRIS CORP. IS DIRECTLY ON POINT AND MUST BE
CONSIDERED.

The jury rendered a verdict of infringement of the asserted claims, but did not specify which limitations were met by equivalents. Thus the record does not reveal whether the particular limitation of "self-erecting" was found literally or equivalently. Following the close of briefing in this case, this Court decided Comark Communications Inc. v. Harris Corp., 156 F.3d 1182, 1187, 48 U.S.P.Q.2d 1001, 1005 (Fed. Cir. 1998). This Court articulated the following rule:

Where there is no specific finding by the jury of equivalence as to a particular element, and the defendant has not successfully argued that a particular limitation could not be met literally, the defendant has assumed the burden of proving not only that there is insufficient evidence under *Lear Siegler* for a jury to find that the limitation could be met equivalently, it must also establish that there is no substantial evidence in the record that would permit the jury to find that <u>any</u> limitation has been met by equivalents.

Comark, 156 F.3d at 1189, 48 U.S.P.Q.2d at 1006 (emphasis in original). Thus, in this case, Gaymar and Mallinckrodt must show either that the jury could not have found that the accused blankets literally "self-erect" or that there was not

sufficient evidence on equivalence as to any limitation. If they cannot, this Court must uphold the jury verdict. *See id.* at 1188, 48 U.S.P.Q.2d at 1006.

## A. Neither Gaymar Nor Mallinckrodt Satisfied Its Burden Under Comark.

Gaymar and Mallinckrodt did not argue on appeal that the jury could not have found that their blankets literally self-erect. Nor did they dispute the trial court's instruction that self-erecting means the blanket "forms a curved or arched structure which stands off the patient." Add. at 11. Instead, Appellants focused their argument on the sufficiency of the evidence to support a finding of infringement as to any of the five disputed elements under the doctrine of equivalents. This Court did not analyze and should not reasonably find that the self-erecting limitation could not literally have been met under the instruction given, nor did this Court rule that there was insufficient evidence to find any element by equivalents.

## B. The Record Demonstrates That The Jury Could Have Found Literal Infringement Of The "Self-Erecting" Limitation.

This Court noted the following evidence in the record:

With respect to the other patents, the magistrate judge detected a genuine issue of material fact relative to the "self-erecting" limitation. Specifically, the magistrate judge noted that "the Mallinckrodt blanket move[d] slightly away from the person underneath it and assume[d] a shape over the person" when in operation. When considering the Gaymar blanket, the magistrate judge explained that "the blanket lift[ed] slightly away from the table as it [was] inflated."

Add. at 8. Based on this evidence, both the magistrate and the trial court "identified the same issue of material fact regarding whether Gaymar's and Mallinckrodt's blankets <u>literally or equivalently</u> self-erect." *Id.* at 9 (emphasis added). The trial court submitted <u>literal</u> and equivalent infringement to the jury and this Court did not find any fault with the charge to the jury regarding the definition of self-erecting; in fact, this Court affirmed the trial court's claim definition: "the district court correctly construed the term 'self-erecting' to require that the accused blankets form a curved or arched structure which stands off the patient." Add. at 11. The jury properly could have found literal self-erecting because when the accused blankets are inflated over a patient, they "move slightly away from the person," and the "shape" that they assume is literally "a curved or arched structure which stands off the patient."

## C. The Literal Scope Of "Self-Erecting" Was Not And Should Not Be Limited To The Scope Of Dependent Claims Directed To A "Self-Supporting" Blanket.

This Court apparently misapprehended the jury's general verdict of equivalents to have been a verdict specifically directed to the self-erecting limitation. If not, then the Court must have assumed that either (i) none of the other disputed limitations could have been found equivalently as opposed to literally, or (ii) that "forming a curved or arched structure which stands off the

patient" means the same as "self-supporting." As to the other disputed elements, days of trial were devoted to Appellants' arguments that they did not have "seams" and "chambers" and to Augustine's showing that the accused blankets had at least the equivalents of seams and chambers. Augustine's Principal Brief at 19-29. Any of these other disputed elements easily could have been found by equivalents.

This Court should not rule that "forming a curved or arched structure which stands off the patient" means "self-supporting" or "does not touch the patient." This construction would be contrary to the one adopted by the trial court and nominally approved by this Court, and would violate the doctrine of claim differentiation. See Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1277, 35 U.S.PQ.2d 1035, 1041 (Fed. Cir. 1995). The term "self-supporting," which may reasonably be construed to prohibit contact with the patient, is a limitation of dependent claim five of the '188 patent. The independent claims, which lack the limitation "self-supporting," should not be read to have the same scope. The parties did not brief or argue this issue of claim differentiation because the Appellants did not contest the trial court's definition.

Other dependent claims in the other patents make it clear that the tubes needed to form a self-supporting blanket are not a limitation of the asserted

independent claims. For example, claim 1 of the '102 patent is directed to a plurality of "chambers" rather than tubes. Dependent claim 10 adds the limitation of "mutually parallel, communicating tubular chambers." The specifications of each of the patents further note that "tubes are preferred since they impart shape and strength to the erected bathing structure; other inflatable structures are contemplated, however." (Emphasis added.) JA04430 col. 4 ll. 63-66; JA04631 col. 4 ll. 33-36; JA05038 col. 5 ll. 31-34. The clear teaching is that neither shape nor strength nor tubes — the hallmarks of a self-supporting blanket — are limitations of the independent claims.

Although Augustine argued for an even broader reading of self-erecting -simple inflation of the blankets under air pressure alone -- to show that JMOL
might have been required in Augustine's favor, no party suggested on appeal that
the literal scope of self-erecting should be as narrow as self-supporting.
Augustine merely pointed out that under a broader construction of "self-erecting,"
this Court might find the "self-erecting" limitation literally met as a matter of law
and might find that all of the other disputed limitations were literally or
equivalently present as a matter of law. The only narrow definition of "selferecting" that still respects claim differentiation is the one given by the trial court

-- and not "self-supporting" -- which renders literal presence of the self-erecting element a question of fact properly submitted to the jury.

D. A Rehearing Is Necessary To Consider The Question Of Literal, Infringement Of The Claim Limitation "Self-Erecting" Based On The Record.

Under *Comark*, this Court "cannot presume to ascertain which elements the jury found to be met only by equivalents." *Comark*, 156 F.3d at 1188, 48 U.S.P.Q.2d at 1006. This Court did presume that the jury in this case found infringement of the term self-erecting only by equivalents. Because this Court did not address literal infringement in its opinion, a rehearing is necessary.

#### **ARGUMENT - SUGGESTION FOR REHEARING IN BANC**

I. THE PANEL'S DECISION IS IN CONFLICT WITH THIS COURT'S DECISION IN COMARK COMMUNICATIONS INC. V. HARRIS CORP. REGARDING JURY VERDICTS WHERE THE VERDICT FORM DOES NOT STATE WHETHER A PARTICULAR LIMITATION WAS FOUND LITERALLY OR EQUIVALENTLY.

As fully explained in the Petition for Rehearing Argument Part I, *supra*, this Court's decision in *Comark* applies when a jury returns a verdict of infringement by the doctrine of equivalents and the verdict form does not state which elements were found literally and which were found equivalently. *Comark Communications Inc. v. Harris Corp.*, 156 F.3d 1182, 1187, 48 U.S.P.Q.2d 1001, 1005 (Fed. Cir. 1998). The decision of the panel in the present case assumes, without proof of any kind, that a particular limitation was found equivalently.

The decision in *Comark* is correct. The Court must uphold jury verdict's of the nature in question "if there is sufficient evidence of equivalents and linking testimony such that a reasonable jury could have found that at least one element, was met by equivalents." *Comark*, 156 F.3d at 1188, 48 U.S.P.Q.2d at 1006. Otherwise the Court is only guessing as to what the jury found. A rehearing in banc is necessary to ensure consistency in the application of the rule announced in *Comark* and to avoid confusion and uncertainty among the trial bench and bar.

# II. WHETHER THE SCOPE OF PROSECUTION HISTORY ESTOPPEL SHOULD BE DECIDED AS A MATTER OF LAW OR OF FACT IS A OUESTION OF EXCEPTIONAL IMPORTANCE.

Appellants put into evidence the application and scope of prosecution history estoppel in this case, including the nature of the doctrine, the statements creating an estoppel in this case and the scope of the estoppel. Trial Transcript, August 20, 1997, pp. 52-55 ll. 19-21; Trial Transcript, August 21, 1997, pp. 122-123 ll. 24-9; JA03960-03961 ll. 20-9. They argued the scope of estoppel to the jury in detail. At their request, the jury was instructed to consider whether Augustine could prevail consistently with the statements in the file history. The specific instruction given is as follows:

- 19 The history of the prosecution of the patent
- application, that's called the file record or the written
- 21 correspondence, for the applicant to the patent office is
- 22 used to explain the meaning of the words used in the patent

- 23 claims. That's the file, wrapper, stuff you've been given.
- 24 A patent owner is estopped, you know the legal term, is
- 25 prevented from taking a position that is inconsistent with

197

- the positions that the patentee took when attempting to
- 2 convince the patent trademark office to issue the patent.
- 3 This is called the document prosecution history
- 4 estoppel.

JA04186-04187 II. 20-5. Thus, Appellants specifically asked the jury to make a factual finding as to the existence and scope of any estoppel. Having lost their gamble with the jury, Appellants now seek a second bite at the apple.

A. The Jury's Verdict Included The Jury's Consideration Of Estoppel And It Cannot Be Set Aside Without Offending The Seventh Amendment To The United States Constitution.

This Court and the Supreme Court have clearly established that the Seventh Amendment to the United States Constitution preserves the right of jury trial in patent cases. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 116 S. Ct. 1384, 1389 (1996); *Paltex Corp. v. Mossinghoff,* 758 F.2d 594 (Fed. Cir. 1985). This Court has also explained that the scope of prosecution history estoppel depends upon a fact finding: what a reasonable competitor is entitled to conclude from a reading of the file history. *Haynes International Inc. v. Jessop Steel Co.*, 8 F.3d 1573, 28 U.S.P.Q.2d 1652 (Fed. Cir. 1993), *on reh'g*, 15 F.3d 1076, 29 U.S.P.Q.2d 1958 (Fed. Cir. 1994); *see also Modine Mfg. Co. v. U.S. Intern. Trade* 

Com'n, 75 F.3d 1545, 1551 (Fed. Cir. 1996), cert. denied, 116 S. Ct. 1523 (1996) (explaining that the standard for determining the scope of estoppel is based on the reasonable reading, by a person of skill in the field of the invention, of the entire prosecution history). Where, as here, the jury is instructed to consider and rule on factual predicates to legal issues and returns a general verdict unaccompanied by the specific fact finding, the verdict includes the fact finding by necessary implication. E.g., DMI, Inc. v. Deere &Co., 802 F.2d 421 (Fed. Cir. 1986). In short, the jury's verdict in this case necessarily included a fact finding that reasonable competitors are not entitled to conclude that the scope of any estoppel surrendered the subject matter of the accused blankets.

The panel substituted its judgment for that of the jury with respect to the underlying factual predicate that determines the scope of estoppel. Although this Court has often announced that prosecution history estoppel is an issue of law for the court, counsel has found no specific guidance as to the jury's role in the specific factual predicate underlying the scope of estoppel. The patent bar and the trial bench would benefit substantially from consideration by this Court in banc whether juries should be permitted to consider the underlying factual question of what reasonable competitors may conclude from file histories and from clarification of what the legal standard for trial judges and on review should be,

when juries are asked to and find the scope of estoppel does not extend to the accused equivalent.

Moreover, having ruled that factual issues in patent cases are the subject of the right to jury trial, and having announced that the test for estoppel is a question which clearly depends on underlying factual questions, this Court has left uncertain the role of the Seventh Amendment in cases of prosecution history estoppel. Upon reconsideration in banc, Augustine would urge that the right to jury trial should include the underlying factual question of the scope of estoppel. Counsel would show that under the present state of the Court's jurisprudence, the right to jury trial in patent cases is materially diminished by de novo review in all cases, regardless of the basis for the jury's verdict.

#### **CONCLUSION**

For the foregoing reasons, Augustine Medical, Inc.'s petition for rehearing and suggestion for rehearing in banc should be granted.

Date: June 21, 1999

OPPENHEIMER WOLFF & DONNELLY LLP

By\_

Jacob M. Holdreith, #211011 Craig J. Lervick, #225368 Elizabeth A. Wefel, #251951 Cyrus A. Morton, #287325

3400 Plaza VII Building 45 South Seventh Street

Minneapolis, Minnesota 55402

Telephone: (612) 607-7000 Facsimile: (612) 607-7100

J. Randall Benham, #154726 Telephone: (612) 947-1200

ATTORNEYS FOR PLAINTIFF-CROSS-APPELLANT AUGUSTINE MEDICAL, INC.

### United States Court of Appeals for the Federal Circuit

98-1001, -1002,-1054,-1244,-1268

AUGUSTINE MEDICAL, INC.,

Plaintiff-Cross Appellant,

GAYMAR INDUSTRIES, INC. and MEDISEARCH P R. INC.,

Defendants-Appellants,

and

MALLINCKRODT GROUP, INC. and MALLINCKRODT MEDICAL, INC.,

Defendants-Appellants.

J. Randali Benham, Augustine Medical, Inc., of Eden Prairie, Minnesota, argued for plaintiff-cross appellant. With him on the brief were Jacob M. Holdreith, Craig J. Lervick, and Robert M. Rauker, Oppenheimer Wolff & Donnelly LLP, of Minneapolis, Minnesota.

Robert J. Lane, Jr., Hodgson, Russ, Andrews, Woods & Goodyear, LLP, of Buffalo, New York, argued for defendants-appellants Gaymar Industries, Inc., et al.

Raymond A. Kurz, Rothwell, Figg. Ernst and Kurz, of Washington, D.C., argued for defendants-appellants Mallinckrodt Group, Inc., et al. With him on the brief was G. Franklin Rothwell.

Appealed from: U.S. District Court for the District of Minnesota

Judge James M. Rosenbaum

# This USPTO date stamp hereon will acknowledge receipt of:

COMMUNICATION

S	Assignee: Serial No.: Filed:	Augustine Medical, Inc. 08/419,719 04/10/95	
	Enclosur <del>e</del> s: Mailed:	Transmittal Form; copies of Notice, Form For Filing A Patent Application CFR 1.60, Filing Receipt; and one repostcard.    Manual Against Again	n Under 37
	TAM/jiv AUGA010000 103806-15395	10	RECEIVED MAY 0 3 2002
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Applicate Assigned Serial Not Filed: Enclosure	onic August August August 104/10  Transi Form CFR 1	stine et al stine Medical, Inc. 9,719 /95 mittal Form; copies of Notice, Request For Filing A Patent Application Under	MAR O 1 1899 S
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PTO/SB/21 REV 1 (12/97)
Approved for use through 09/30/2000. omb 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Act of 1995, no persons are required to respond to a collection of

mation unless it displays a valid OMB control		VOIR REGULATION ACT OF 1995, NO	persons are required to respond to a consecutor
		Application Number	08/419,719
		Filing Date	04/10/95
TRANSMITTAL F	ORM	First Named Inventor	Augustine et al
(to be used for all correspondence after		Examiner Name	Graham
		Group Art Unit	3304
tal Number of Pages in This Submission	1 7	Attorney Docket Number	AUGA01000010
	ENCLOSURE	ES (check all that apply)	
_ Fee Transmittal Form	Assignment (for an Appl		After Allowance Communication to Group
Fee Attached Amendment/Response	Drawing(s)	elated Papers	Appeal Communication to Board of Appeals and Interferences
<del>-</del> .			Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
After Final	Petition Che Accompany		Proprietary Information
Extension of Time Request	To Convert		Status Letter
_ Express Abandonment Request	Provisional		X Additional Enclosure(s)
Information Disclosure Statement PTO Form 1449	-	torney, Revocation	(please identify below):
(no.) cited references	Change of C	Correspondence Address	POSTCARD
Certified Copy of Priority Document(s)	Terminal Dis	sclaimer	
Response to Missing Parts/			
Incomplete Application	Remarks:		
PTO Form 1533	COMMUNIC	ATION	
Response to Missing Parts Under 37 CFR 1.52 or 1.53	COMMONIC	ATION	
	SIGNATURE OF APPI	LICANT, ATTORNEY, OR AGEN	т
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### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applicat	ion of:		)	
S.D. AUGUS	ΓΙΝΕ ΕΤ AL.		)	Group Art Unit: 3304
Serial No.:	08/419,719	,	)	
Filed:	April 10, 1995		)	Examiner: M. Graham
For: THER	MAL BLANKET		,	•
Assistant Con Washington, I ATTN: Mark				

### **COMMUNICATION**

On June 2, 1997, a Notice (Paper No. 19) was mailed from the Office of Patent Publication to the undersigned. A copy of the paper is attached. The purpose of the Paper was to give notice that the subject patent application was withdrawn from issue by the Office for the purpose of reopening prosecution. The Notice indicated the application was being returned to the Office of the Director of Group 3300. Since the June 2, 1997 Notice, we have received no further communication from the Patent Office regarding this matter.

On May 21, 1997, a Rule 60 Continuation was filed in this application. A copy of the Continuation Request is also attached. The Official Filing Receipt for this Continuation, copy attached, indicated that the subject application, Serial No. 08/419,719 had been abandoned. As evidenced by the Continuation Request, no abandonment was requested.

1

P:\AUGUSTIM153959.COM

Sir:

The undersigned respectfully requests information as to the status of this application and the location of its file.

Respectfully submitted,

Date: 1/14/1/999

TERRANCE A. MEADOF

Reg. No. 30,298

GRAY CARY WARE & FREIDENRICH 401 B Street, Suite 1700 San Diego, California 92101

Telephone (619) 699-2652 Fax (619) 236-1048

### RECEIVED

JUN 04 1997

RIP Baker, Maxham, Joster & Meack



UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

Patent and Trademark Office ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS Washington, O.C. 20231

Paper No.19

TERRANCE A. MEADOR BAKER, MAXHAM, JESTER & MEADOR SYMPHONY TOWERS 750 "B" STREET, SUITE 3100 SAN DIEGO, CALIFORNIA 92101

COPY MAILED

JUN 02 1997

OFFICE OF PATENT PUBLICATION

In re Application of Scott D. Augustine, et al. Application No. 08/419,719 Filed: April 10, 1995 Attorney Docket No. 1342-119

NOTICE

The purpose of this communication is to inform you that the above - identified application, which has received a patent number or an issue date, is being withdrawn from issue pursuant to 37 CFR 1.313.

The application is being withdrawn for the following purpose: to reopen prosecution. This withdrawal was requested by the Group Director. Any questions concerning this withdrawal should be addressed to the Group Director.

This application is being returned to the Office of the Director of Group 3300.

Telephone inquiries concerning this matter may be directed to the undersigned at (703) 308-5254.

Karna Cooper

Paralegal Specialist
Office of the Director

Office of Patent Publication

DOCKETED

JUN - 4 1997

FILF \$42-118 k

### REQUEST FORM FOR FILING A PATENT APPLICATION UNDER 37 CFR 1.60

DATE: May 21, 1997

DOCKET NUMBER	1	PATED CLASSIFICATION THIS APPLICATION	PRIOR APPLICATION EXAMINER	ART UNIT
1342-188	CLASS:	SUBCLASS:	M. Graham	3304

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ASSISTANT COMMISSIONER FOR PATENTS

Washington, D.C. 20231

fhis is a Request for filing a <u>X</u>	_ continuation	 divisional	' application un	ler 37	CFR	1.60,	of pending	application Number	08/419,719,	filed on
April 10, 1995 entitled THERMAI	L BLANKET									

Enclosed is a copy of the latest inventor-signed prior application, including a copy of the oath or declaration showing the original signature or an indication it was signed. I hereby verify that the papers are a true copy of the latest signed prior application number 08/419,719, and further that all statements made herein of my own knowledge are true; and further that these statements were made with the knowledge that willful false statements and the like are made punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issuing thereon.

0) 44440	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
CLAIMS	TOTAL CLAIMS	25 20 -	5	x \$ 22.00 -	\$ 110.00
	INDEPENDENT CLAIMS	8 · 3 -	5	x \$ 80.00 -	\$ 400.00
-	MULTIPLE DEPENDENT CLAIR	MS (if applicable)		+ \$ 260.00 -	.\$
		4 4.15. 38		BASIC FEE	\$ 770.00
		Andrew Co.	1	ove Calculations -	\$ 1,280.00
	Reduction by 50% for filing a	Small Entity (Note 37 C	FR 1.9, 1.27, 1.28).		
				TOTAL =	\$ 640.00

2. X A verified statement to establish small entity status under 37 CFR 1.9 and 1.27  X is enclosed. X was filed in prior application number 08/419,719 and such status is still proper and desired (37 CFR 1.28(a)).  3. X The Commissioner is hereby authorized to charge any fees which may be required under 37 CFR 1.16 and 1.17, or credit any overpayment Deposit Account No. 02.0460. A duplicate copy of this sheet is enclosed.  4. X A check in the amount of \$640.00 is enclosed.  5. Cancel in this application original claims of the prior application before calculating the filing fee. (At le one original independent claim must be retained for filing purposes.)  6. X Amend the specification by inserting before the first line the sentence: "This application is a continuation of application number 08/419,7 filed April 10, 1995, which is."  7. Transfer the drawings from the pending prior application to this application and abandon said prior application as of the filing date accorded to application. A duplicate copy of this sheet is enclosed for filing in the prior application. (May only be used if signed by person authorized 37 CFR 1.138 and before payment of issue fee.)  8. X New formal drawings are enclosed (5 Sheets).  [Page 1 of 2 ] Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE				TOTAL = 3 040,00
Deposit Account No. <u>02.0460</u> . A duplicate copy of this sheet is enclosed.  1. X A check in the amount of \$ 640.00 is enclosed.  2. Cancel in this application original claims of the prior application before calculating the filing fee. (At le one original independent claim must be retained for filing purposes.)  3. X Amend the specification by inserting before the first line the sentence: "This application is a continuation of application number 08/419,7 filed April 10, 1995, which is."  3. Transfer the drawings from the pending prior application to this application and abandon said prior application as of the filing date accorded to application. A duplicate copy of this sheet is enclosed for filing in the prior application. (May only be used if signed by person authorized 37 CFR 1.138 and before payment of issue fee.)	2. <u>)</u>	X is enclosed.		
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(2-92) [Page 1 of 2] Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE	3	X New formal drawings are enc	losed (5 Sheets).	
		(2-92)	(Page 1 of 2 )	Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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9.	Priority of foreign application number	, filed on	i	in	is
	claimed under 35 U.S.C. 119.				
	The certified copy has been filed in prior applicat	tion numberI	, filed	·	
10	A preliminary amendment is enclosed.			•	
11. <u>X</u>	The prior application is assigned of record to AUGUST	NE MEDICAL, INC.			
12. <u>X</u>	Also enclosed: (7) Information Disclosure Statements	& PȚO Form 1449's fr	om the parent case Serial	No. 08419,719, filed April 10	), 1995.
13. <u>X</u>	The power of attorney in the prior application is to: (na	med & address):			
	Terrance A. Meador, #30,298				
	BAKER, MAXHAM, JESTER & MEADOR 110 West "C" Street, Suite 1202				
	San Diego, California 92101				
	X The power of attorney appears in the original pa Since the power does not appear in the original pa	pers in the prior applic papers, a copy of the p	ation. ower in the prior applicati	ion is enclosed.	
c	X Address all future correspondence to: (May only	be completed by applic	ant, or attorney or agent	of record.)	
	Terrance A. Meador, #30,298				
	BAKER, MAXHAM, JESTER & MEADOR	:			
	Symphony Towers 750 "B" Street, Suite 3100			•	
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_	orney or agent of record ed under 37 CFR 1.34(a)				
	Registration number if acting under 37 CFR 1.34(a).				
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(Page 2 of 2)

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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TERRANGE A MEADOR
BAKER MAXHAM JESTER & MEADOR
SYMPHONY TOWERS
750 B STREET SUITE 3100
SAN DIEGO (CA 19 2101

Receipt is technowledged of the group overload Petent Application. It will be considered in its order and you will be notified, as go results of the examination. Be sure to provide the U.S. (APPLICATION) NUMBER, FILING DATE, NAME OF NAPILICANT, and TITLE OF INVENTION, when linguishing about this application by ees transmitted by check or draft are subject to production. Please verify the second this test presented for this product of the value presented on this product of the value presented on this product of the value presented on the product of the value presented of the value presented on the product of the value prod

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CHANGE OF ADDRESS

Serial No.: 08/419, 719

Filed: 4-10-95

Mailed: 27 Ax: 1 1998

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File No.: 1342-119

Filed: 4-10-95

Mailed: 27 Ax: 1 1998

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Filed: 1998

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File No.: 1342-119

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent Application Serial No. 08/419,719

Inventor: Augustine, et al

Group: 3304

Filed:

Examiner: A. Broham

CERTIFICATE OF MAILING

37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C., 20231, on the date below:

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

## REQUEST FOR CHANGE OF ADDRESS

This is to notify the Office that all correspondence in the subject matter should be addressed to:

TERRANCE A. MEADOR GRAY CARY WARE & FREIDENRICH 4365 EXECUTIVE DRIVE, SUITE 1600 SAN DIEGO, CA. 92121-2189

RESPECTFULLY SUBMITTED

Terrance A. Meador Registration No. 30,298

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611-O THA DEMARK OFTO November 17, 1997 4581 6 1 MM :paj s cyeck tor \$240 Cited references PTO Form 1449 :Tosnres: April 10, 1995 617,814/80 Augustine Medical, Inc. :rial No.: S.D. Augustine et al :∍∮ngie; INFORMATION DISCLOSURE STATEMENT For "Inflatable Lower Body "hermal Richard" (2 nos + a conv) he USPTO date stamp hereon acknowledges receipt of: manageren Sonat (j. 1881) Sonat antiquit jage Body "Inflatable Lower of: φ. stamp hereon acknowledges receipt S.D. Augustine et al Augustine Medical, Inc. 08/419,719 April 10, 1995 MAY 0 3 2002 INFORMATION DISCLOSURE STATEMENT For Thermal Blanket" (2 pgs. + a copy) OFFICE OF PETITIONS PTO Form 1449 Cited references a check for \$240 date Assignee: Serial No.: TAM/jiv 1342-119

Case 1342119 Description 1342-119 (TAM) IDS USPTO Date 11/17/97 Prono Vouch

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"PATENT"

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re A	Applicat	ion of:	)			
S.D. AUGUSTINE, ET AL.			)	Group Art U	Jnit:	3304
Serial 1	No.:	08/419,719	)			
Filed:		April 10, 1995	)	Examiner:	M. G	raham
For:		TABLE LOWER BODY MAL BLANKET	) .)			

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

#### CERTIFICATE OF MAILING 37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date below:

17 Nove mon 1997 Tenancia Mesos Date Signature

### INFORMATION DISCLOSURE STATEMENT

Applicant hereby cites the documents listed in accompanying Form PTO-1449 with respect to the above-referenced patent application under the provisions of 37 C.F.R., Sections 1.56, 1.97 and 1.98. Copies of the documents are attached.

This information is submitted in order to keep the Examiner apprised of the status of U.S. Patent No. 5,405,371, which issued from a predecessor application - No. 638,748, filed 8 January 1991.

[F:\CLIENT\1342\119\IDS.TMT]

A check in the amount of \$240 is enclosed in accordance with § 1.97(c) is enclosed. Please charge or credit Deposit Account 02-0460 any discrepancy. A duplicate of this paper is enclosed.

Respectfully submitted,

TERRANCE A. MEADOR

Reg. No. 30,298

BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 B Street, Suite 3100 San Diego, California 92101

Telephone (619) 233-9004

Fax (619) 544-1246

"PATENT"

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re A	pplicati	ion of:	)			
S.D. AUGUSTINE, ET AL.			)	Group Art U	nit:	3304
Serial 1	No.:	08/419,719	)			
Filed:		April 10, 1995	)	Examiner:	M. Gr	aham
For:		TABLE LOWER BODY MAL BLANKET	) )	:		

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

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### INFORMATION DISCLOSURE STATEMENT

Applicant hereby cites the documents listed in accompanying Form PTO-1449 with respect to the above-referenced patent application under the provisions of 37 C.F.R., Sections 1.56, 1.97 and 1.98. Copies of the documents are attached.

This information is submitted in order to keep the Examiner apprised of the status of U.S. Patent No. 5,405,371, which issued from a predecessor application - No. 638,748, filed 8 January 1991.

[F:\CLIENT\1342\119\IDS.TMT]

A check in the amount of \$240 is enclosed in accordance with § 1.97(c) is enclosed. Please charge or credit Deposit Account 02-0460 any discrepancy. A duplicate of this paper is enclosed.

Respectfully submitted,

TERRANCE A. MEADOR

Reg. No. 30,298

BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 B Street, Suite 3100 San Diego, California 92101

Telephone (619) 233-9004

Fax (619) 544-1246

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Form PTO 1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use Several Sheets If Necessary)			Docket No.	Docket No. 1342-119 Application No. 08/419,719			19	
			Applicant: S	Applicant: S.D. Augustine et al				
			Filing Date:	04/10/95	Group Art U	Group Art Unit 3304		
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### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Reexamination of U.S. Patent No. 5,405,371	)	
Inventors:	S. D. Augustine et al.	)	· ·
Control No:	90/004,529	)	
Filed:	January 23, 1997	)	Group Art Unit: Special Program Law Office
Title:	THERMAL BLANKET	)	
Docket No:	8847/300	)	Examiner: L. Anderson

Commissioner of Patents and Trademarks Washington, D.C. 20231

I hereby certify that this Communication to Examiner was transmitted by facsimile to the Commissioner of Patents and Trademarks, Washington, D.C. 20231, on October 2007

Rita M. McAloon, Secretary to Craig J. Lervick

### **COMMUNICATION TO EXAMINER**

Dear Sir:

The following is an update pursuant to 37 C.F.R. 1.565(a).

In the cases of <u>Augustine Medical</u>, <u>Inc. v. Gaymar Industries</u>, <u>Inc. et al.</u> and <u>Augustine Medical</u>, <u>Inc. v. Mallinckrodt Medical</u>, <u>Inc. et al.</u> (the "litigation"), which has previously been identified in this proceeding, judgment in favor of Augustine Medical, Inc. was entered on September 26, 1997. By so entering judgment, the Court incorporated all previous orders and findings into its final judgment, including, but not limited to: (1) the January 28, 1997 order granting of defendant's motion for summary judgment of invalidity of claims 1, 3, 4 and 8 of U.S. Patent No. 5,405,371, and (2) the jury's verdict finding valid, enforceable and infringed

claims 2, 5, 6, 7, and 9 of U.S. Patent No. 5,405,371. The time period for appeal from this judgment has not yet passed.

Respectfully submitted,

S. D. AUGUSTINE et al., Applicants

Date: October <u>21</u>, 1997

Craig J. Lervick, Attorney Reg. No. 35,244 Oppenheimer Wolff & Donnelly

3400 Plaza VII

45 South Seventh Street

Minneapolis, Minnesota 55402

Telephone: (612) 607-7387

Fax: (612) 607-7100

Attorney for Applicants

## CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the following correspondence is being transmitted by facsimile to the Patent and Trademark Office on the date shown below.

Date

1. Communication to Examiner.

Signature Rita M. McAloon Octob



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UNITED STA , DEPARTMENT OF COMMERCE Patent and Trademark Office ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

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Terrance A. Meador Baker Maxham Jester & Meador Symphony Towers Suite 3100 750 B Street San Diego, CA 92101

(For Patent Owner)

MAILED OCT 28 1997 REEXAM UNIT

In re reissue application of Augustine, et al. Serial No. 08/658356 Filed: June 5, 1996

For: U.S. Patent No. 5,405,371

In re Augustine, et al. Reexamination Proceeding Control No. 90/004,529 Filed: January 23, 1997 For: U.S. Patent No. 5,405,371 DECISION, SUA SPONTE, TO MERGE REEXAMINATION AND REISSUE PROCEEDINGS

The above noted reexamination file and reissue application are before the Office of the Deputy Assistant Commissioner for Patent Policy and Projects, <u>sua sponte</u>, for a decision on whether the proceedings should be merged at this time.

### **REVIEW OF FACTS**

- 1) U.S. Patent No. 5,405,371 issued April 11, 1995.
- 2) On June 5, 1996, a reissue application was filed by the patent owner. In the reissue, Patent Owner deleted the words "self-erecting" from claims 1, 4, 8 and 9. He also added dependent claims 10-20.
- 3) In an Office action dated October 28, 1996, the examiner rejected claims 1-9 based on a defective reissue declaration. Claims 10 20 are not commented upon.

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- 4) On November 18, 1996, in related litigation in the United States District Court, District of Minnesota, Fourth Division, Case Nos. 4-94-CV-875, et al., in response to a defendant's motion for summary judgement, claims 1, 3, 4, and 8 were recommended as being invalid by the Magistrate Judge.
- 5) On January 10, 1997, a request for reexamination of the patent was filed by the patent owner.
- 6) On January 28, 1997, the decision of the Magistrate Judge was adopted by the District Court which found claims 1, 3, 4 and 8 of the '371 patent to be invalid.
- 7) On April 9, 1997, reexamination was ordered on the basis that there was a significant question of patentability concerning claims 1, 3, 4 and 6, and additionally the claims 2, 5 and 7 9.
- 8) On April 22, 1997, in the reissue application, an Office action issued suspending prosecution for four months.
- 9) On September 26, 1997, in the cases of Augustine Medical, Inc. v. Gaymar Industries, Inc. and Augustine Medical, Inc. v. Mallinckrodt Medical, Inc., the United States District Court, District of Minnesota, Fourth Division, entered judgment in favor of Augustine Medical, Inc. (Patent Owner). By so entering judgment, the District Court incorporated all previous orders and findings into its final judgment, including the January 28, 1997 order granting defendant's motion for summary judgment of invalidity of claims 1, 3, 4 and 8 of the '371 patent and the jury's verdict finding valid, enforceable and infringed claims 2, 5, 6, 7 and 9 of the '371 patent.

#### **DISCUSSION**

Under 37 CFR § 1.565(d):

(d) If a reissue application and a reexamination proceeding on which an order pursuant to § 1.525 has been mailed are pending concurrently on a patent, a decision will normally be made to merge the two proceedings or to stay one of the two proceedings....

As evidenced by the above review of facts, the reissue application and the reexamination proceeding are currently pending. As the order to reexamine has been mailed in the reexamination proceeding, a decision under § 1.565(d) is timely.

The general policy of the Office is that a reissue application examination and a reexamination proceeding will not be conducted separately at the same time as to a particular patent. The reasons for this policy is to prevent inconsistent, and possible conflicting amendments from being introduced into the two proceedings on behalf of the patent owner. Normally the proceedings will be merged whenever it is desirable to do so in the interest of expediting the prosecution of

both proceedings. In making a decision on whether or not to merge the two proceedings consideration will be given to the status of each proceeding. See MPEP 2285.

A review of the reissue prosecution history shows that the announcement of the filing of the reissue application was published in the Official Gazette on January 28, 1997, thereby permitting the issuance of a first action on the merits after March 28, 1997. 37 CFR § 1.176. New claims have been added in the reissue application. A review of the reexamination file shows that the reexamination is awaiting an Office action by the examiner. The original specification, drawings and patent claims are presently in the reexamination file. The claims are not identical in both proceedings. In order to provide efficient and prompt handling of both proceedings and to prevent inconsistent, and possibly conflicting amendments from being introduced on behalf of the patent owner, it is appropriate that the reissue and the reexamination proceeding be merged and a joint examination be conducted. Accordingly, the examination of the reissue application and the reexamination will be in accordance with the decision set forth below.

#### DECISION

### I. Merger of Proceedings

The above noted reissue and reexamination proceedings are, <u>sua sponte</u>, merged. A joint examination will be conducted in accordance with the following guidelines and requirements.

### II. Requirement for Same Amendments in Both Proceedings

The patent owner is required to maintain identical amendments in the reissue application and the reexamination file for purposes of the merged proceedings. The maintenance of identical amendments in the two files is required as long as the proceedings are merged. See 37 CFR § 1.565(d). An appropriate housekeeping amendment is required within one month of this decision placing the same amendments in both proceedings. The patent owner should not address the issues of either proceeding in the housekeeping amendment.

## III. Conduct of the Merged Reissue Application Examination and Reexamination Proceeding

In view of the fact that the statutory provisions for reissue application examination include, inter alia, provisions equivalent to 35 U.S.C. § 305 relating to the conduct of reexamination proceedings, the merged examination will be conducted on the basis of the rules relating to the broader reissue application examination. The examiner will apply the reissue statute, rules and case law to the merged proceeding. The examiner's actions will take the form of a single action which jointly applies to both the reissue application and the reexamination proceeding. The action will contain identifying data for both the reissue application and the reexamination proceeding and will be physically entered into both files which will be maintained as separate files. Any response by the applicant/patent owner must consist of a single response, filed in duplicate, each bearing an

original signature, for entry in both files. Any such responses must be served on the requester who will also be sent copies of Office actions. See 37 CFR § 1.550(e).

If the applicant/patent owner fails to file a timely and appropriate response to any Office action, the merged proceeding will be terminated. The reissue application will be held abandoned and the Commissioner will proceed to issue a reexamination certificate under § 1.570 in accordance with the last action of the Office unless further action is clearly needed in view of the difference in rules relating to reexamination and reissue proceedings.

If the applicant/patent owner files an express abandonment of the reissue application pursuant to 37 CFR § 1.138, the next Office action of the examiner will accept the express abandonment, dissolve the merged proceeding and continue the reexamination proceeding. Any grounds of rejection which are not applicable under reexamination should be withdrawn (e.g., based on public use or sale) and any new grounds of rejection which are applicable under reexamination (e.g., improper broadened claims) should be made by the examiner upon dissolution of the merged proceeding. The existence of any questions remaining which cannot be considered under reexamination following dissolution of the merged proceeding would be noted by the examiner as not being proper under reexamination pursuant to 37 CFR § 1.552(c).

If the reissue application ultimately matures into a reissue patent the reexamination proceeding shall be terminated by the grant of the reissued patent and the reissued patent will also serve as the certificate under § 1.570. See MPEP 2285.

Applicant/patent owner is advised that the filing of (a) a file wrapper continuation (FWC) reissue application under 37 CFR § 1.62 or (b) a continued prosecution (CPA) reissue application under 37 CFR § 1.53 (d), whereby (in either case) the current reissue application is considered to be expressly abandoned, will most likely result in the dissolution of the merged proceeding, a stay of the FWC or CPA reissue application, and separate, continued prosecution of the reexamination proceeding.

It is noted that in the decision of *Ethicon v. Quigg, 7* USPQ2d 1152, 1157 (Fed. Cir. 1988) the Court of Appeals for the Federal Circuit stated:

[1] fa court finds a patent invalid, and that decision is either upheld on appeal or not appealed, the PTO may discontinue its reexamination. This is consistent with Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation, 402 U.S. 313 [169 USPQ 513](1971), which "held that where a patent has been declared invalid in a proceeding in which the 'patentee has had a full and fair chance to litigate the validity of his patent' (402 U.S. at 333 [169 USPQ at 521] . . .), the patentee is collaterally estopped from relitigating the validity of the patent." Mississippi Chemical Corp. V. Swift Agricultural Chemicals Corp., 717 F.2d 1374, 1376, 219 USPQ 577, 579 (Fed. Cir. 1983), quoted in Allen Archery, 819 F.2d at 1091, 2

USPQ2d at 1492. Of course, in the end it is up to a court, not the PTO, to decide if the patentee had a "full and fair chance" to litigate the validity of the patent. But it is admissible for the PTO to act on the standing judgment of invalidity unless and until a court has said it does not have res judicata effect.

Accordingly, the patent claims 1, 3, 4 and 8 finally held invalid by the Federal court will be withdrawn from consideration on the grounds of collateral estoppel. The same will hold true for claims of the same or broader scope as those held to be invalid. With respect to claims raising issues not raised by the litigated claims, the Examiner will follow the analysis set forth by the Court of Appeals for the Federal Circuit in the case of *Interconnect Planning Corporation v. Feil*, 227 USPQ 543,546 (Fed. Cir. 1985). On the other hand, in accordance with MPEP 2242, the finding of *validity* by the District Court "does not necessarily mean that no new question is present, because of the different standards of proof employed by the Federal Courts and the Office." See *Ethicon v. Quigg*, 7 USPQ2d 1152, 1157 (Fed. Cir. 1988).

### IV. Remand for Examination

The above noted reissue application and reexamination proceedings are merged. The reissue application and the reexamination file are being forwarded to the Director of Examining Group 3300 for examination in accordance with this decision.

Inquiries concerning this decision should be directed to the undersigned at (703)305-9285.

Lawrence E. Anderson

Senior Legal Advisor

Special Program Law Office

Office of the Deputy Assistant Commissioner

for Patent Policy and Projects

### RECEIVED

JUN 0 4 1997

RÌP

In re Application of

Baker, Maxham, Jester & Meach



## UNITED STATES DEPARTMENT OF COMMERCE

Patent and Trademark Office ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

Paper No.19

TERRANCE A. MEADOR BAKER, MAXHAM, JESTER & MEADOR SYMPHONY TOWERS 750 "B" STREET, SUITE 3100 SAN DIEGO, CALIFORNIA 92101

**COPY MAILED** 

JUN 02 1997

OFFICE OF PATENT PUBLICATION

Scott D. Augustine, et al. Application No. 08/419,719 Filed: April 10, 1995 Attorney Docket No. 1342-119

NOTICE

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OFFICE OF PETITIONS

The purpose of this communication is to inform you that the above - identified application, which has received a patent number or an issue date, is being withdrawn from issue pursuant to 37 CFR 1.313.

The application is being withdrawn for the following purpose: to reopen prosecution. This withdrawal was requested by the Group Director. Any questions concerning this withdrawal should be addressed to the Group Director.

This application is being returned to the Office of the Director of Group 3300.

Telephone inquiries concerning this matter may be directed to the undersigned at (703) 308-5254.

Karna Cooper

Paralegal Specialist

Office of the Director

Office of Patent Publication

DOCKETED

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BAKER, MAXHAM, JESTER & MEADOR
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SAN DIEGO, CA 92103
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GENERAL ACCOUNT

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# → PART B—ISSUE FEE TRANSMITTAL

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Correspondence address change (Complete only if there is a change) Terrance A. Meador, Esq. BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 "B" Street, Suite 3100 San Diego, CA 92101			page, list to 3 registere OR, alterna having as attorney or	4-For printing on the patent front page, list the names of not more than 3 registered patent attorneys or agents OR, afternatively, the name of a firm having as a member a registered attorney or agent. If no name is listed, no name will be printed.  3				
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### "PATENT" IN AND UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: S.D. Augustine Group No.: 3304 Serial No.: 08/419,719 Examiner: M. Graham . Filed: April 10, 1995 Batch No.: J14 For: INFLATABLE LOWER BODY THERMAL **BLANKET** 

Assistant Commissioner for Patents Washington, D.C. 20231

ATTN: Draftsman

CERTIFICATE OF MAILING

37 C.F.R. 1.8 I hereby certify that this correspondence is being deposited with AND U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington. D.C. 20231, on AND date below:

### TRANSMITTAL OF FORMAL DRAWINGS

Transmitted herewith are FIVE (5) sheets of formal drawings replacing informal drawings previously submitted.

Respectfully submitted,

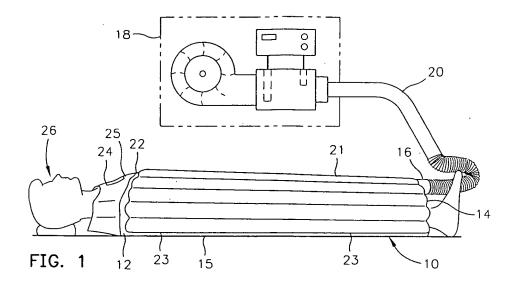
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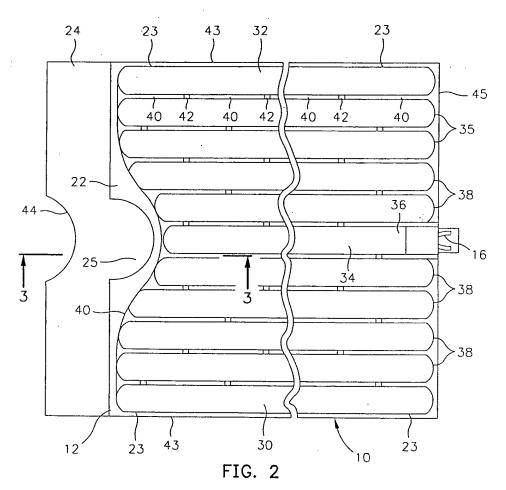
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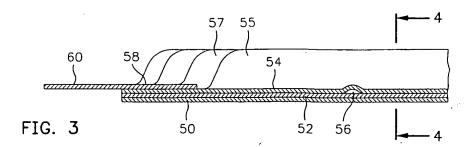
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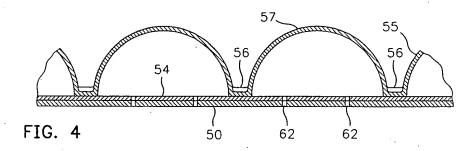
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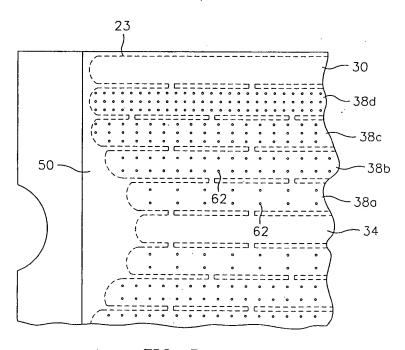
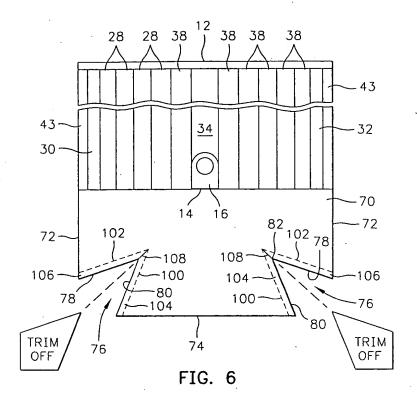
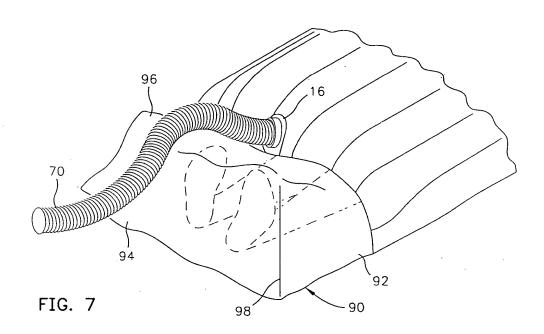


FIG. 5





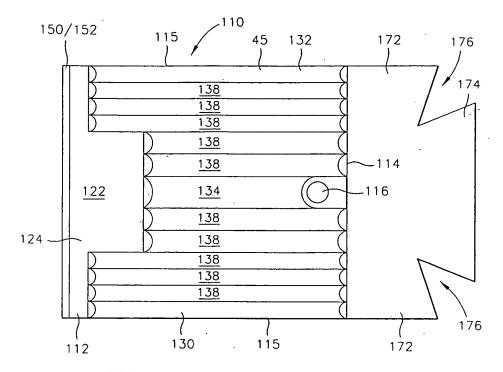
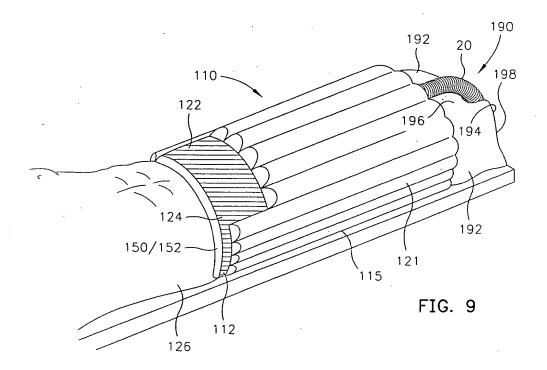
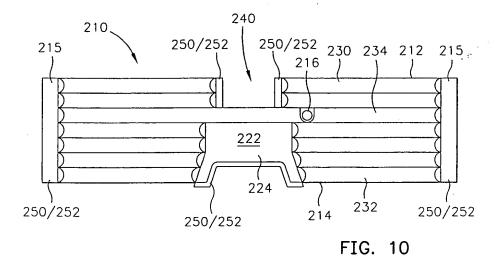
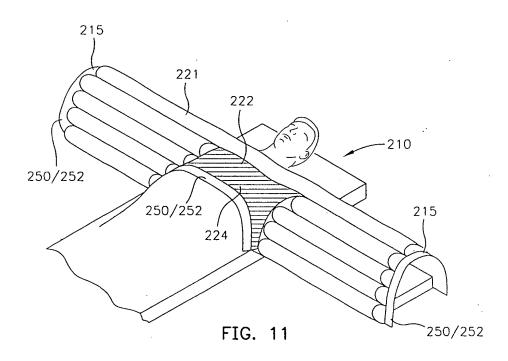


FIG. 8







Petition under 37 CFR 1.97(d)z (in duplicate) INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97(d) for Petition under 37 CFR 1.97(d)z (induplicate) INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97(d) for "Inflatable Lower Body Thermal Blanket" (2 pgs.) 71480 U.S. The USPIO date stamp hereon acknowledges receipt of: PTO Form 1449 & One cited reference . The USPTO date stamp hereon acknowledges receipt of: a check for \$130.00 PTO Form 1449 & One cited reference "Inflatable Lower Body Thermal Blanket" (2 pgs.) S.D. Augustine et al Augustine Medical, Inc. Augustine Medical, Inc. a check for \$130.00 S.D. Augustine et al April 10, 1995 April 10, 1995 Mailed: February 24, 1997 08/419,719 Mailed: February 24, 1997 08/419,719 Assignee: Serial No.: Enclosures: Applicant: Serial No.: Filed: Enclosures: Applicant: Assignee: 1342-119 TAM/jiv

TAM/jiv

17073 Amount 130.00 130.00 Total Paid U.S.P.T.O.
Date Description Case 02/24/97 1342119 PETITION TO COMMISSION 1342119 02/24/97 BAKER, MAXHAM, JESTER & MEADOR A PROFESSIONAL LAW CORPOPATION SYMPHONY TOWERS (619) 223-3004 PTO00 Vouch 10472

GENERAL ACCOUNT

02/24/97 17073

DATE

\*ONE HUNDRED THIRTY AND 00/100 DOLLARS\*

U.S.P.T.O.

PAY TO THE ORDER OF Turneth. Men

#017073# :122234822: 820256401#

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)
S.D. AUGUSTINE, ET AL.	) Group Art Unit: 3304
Serial No.: 08/419,719	)
Filed: April 10, 1995	) Examiner: M. Graham
For: INFLATABLE LOWER BODY THERMAL BLANKET	)
Assistant Commissioner for Patents Washington, D.C. 20231	

Sir:

CERTIFICATE OF MAILING 37 C.F.R. 1.8
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date below:

#### INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97(d)

In satisfaction of their continuing duty of candor and fair dealing, the applicants hereby cite the Order listed on the accompanying Form PTO-1449 with respect to the above-identified patent application under the provisions of 37 CFR, Sections 1.56, 1.97, and 1.98.

This application has been allowed by a Notice dated February 3, 1997. The Batch No. is O10. The issue fee has not been paid.

F::WP60:USERS\ATTY\TAM\AUGUSTIN:1342-119.ID6

No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the statement.

A petition under 37 CFR 1.97(d)z accompanies this statement, as does a check for the fee specified in 37 CFR 1.17(1).

The Examiner is also requested to acknowledge the Information Disclosure Statement submitted on January 24, 1997.

The filing of this Information Disclosure Statement should not be construed to mean that a search was conducted in this application or that no other material information, as defined by 37 CFR 1.56, exists. The Examiner is respectfully requested to make the Order of record, if deemed relevant to the examination of this application.

Respectfully submitted

TERRANCE A. MEADOR Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 "B" Street, Suite 3100 San Diego, California 92101

PHONE:

619/233-9004 FAX: 619/544-1246

# Form PTO 1448 INFORMATION DISCLOSURE CITATION

Docket No. 1342-119

Application No. 08/419,719

IN AN APPLICATION			Applicant: S.D. Augustine et al					
	(Use Several Sheets If	Necessary)		Filing Date: 04/10/95 Group Art Unit 330			nit 3304	
			U.S. PATEN1	DOCUMENTS				
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME		CLASS	SUBCLASS	FILING IF APPRO	
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			FOREIGN PATE	NT DOCUMENTS				
	DOCUMENT NUMBER	DATE	co	UNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
			OTHER DOCUM	ENTS (Including )	Author, Title,	Date, Pertinent	Pages, Etc.)	
	ORDER by United Mallinckrodt Media	States District J a, Inc., U.S. Dis	ludge James M. trict Court, Dist	Rosenbaum, <u>August</u> rict of Minnesota, F	ine Medical, In ourth Division,	nc., v. Mallinckroo Case No. 4-94-C	lt Group, Inc. V-875, Januar	and y 28, 1997.
					-			
XAMINER				DATE CONSIDER	ED			
.AMINER: Init d not consider	ial if citation is considered, w ed. Include copy of this form	thether or not ci	tation is in conf nunication to th	ormance with MPEP e applicant.	§ 609; <b>D</b> raw	line through cita	tion if not in c	onformance

# UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA FOURTH DIVISION 4-94-CV-875

Augustine Me	dical,	Inc.	)	
v.			)	ORDER
Mallinckrodt Mallinckrodt	Group, Medica	Inc. and 1, Inc.	) )	

Plaintiff objects to the Report and Recommendation, issued November 18, 1995, by the Honorable Franklin L. Noel, United States Chief Magistrate Judge. Plaintiff timely filed his objections to the Report, pursuant to Local Rule 72.1(c)(2).

Based upon a <u>de novo</u> review of the record herein, the Court adopts the Magistrate's Report and Recommendation. Accordingly, IT IS ORDERED that:

Defendant's motion for summary judgment of invalidity of claims 1, 3, 4, and 8 of the '371 patent is granted.

Dated: January 24, 1997

JAMES M. ROSENBAUM

United States District Judge

(1/2)

FILES VIEW CONTROL OF THE CONTROL OF

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re App	lication of:	)			
S.D. AUG	GUSTINE, ET AL.	)	Group Art U	nit:	3304
Serial No	.: 08/419,719	)			
Filed:	April 10, 1995	)	Examiner:	M. Gr	raham
	FLATABLE LOWER BODY HERMAL BLANKET	)	•		

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

CERTIFICATE OF MAILING 37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date below:

# PETITION UNDER 37 CFR 1.97(d)z

The Examiner is respectfully petitioned to consider and enter the accompanying Information Disclosure Statement.

F: WP60 USERS ATTY TAM AUGUSTIN 1342-119.PET

The petition fee set forth in 37 CFR 1.17(i) is satisfied by the accompanying check in the amount of \$130. Authorization is hereby given to charge any deficiency to Deposit Account No. 02-0460. This paper is submitted in duplicate.

Respectfully submitted,

TERRANCE A. MEADOR Reg. No. 30,298

BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 B Street, Suite 3100 San Diego, California 92101

Telephone (619) 233-9004

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applica	tion of:	)		
S.D. AUGUS	TINE, ET AL.	)	Group Art Uni	t: 3304
Serial No.:	08/419,719	. )		
Filed:	April 10, 1995	)	Examiner:	M. Graham
	ATABLE LOWER BODY MAL BLANKET	)		
Assistant Con Washington, I	omissioner for Patents D.C. 20231	,		

Sir:

CERTIFICATE OF MAILING 37 C.F.R. 1.8 .

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#### PETITION UNDER 37 CFR 1.97(d)z

The Examiner is respectfully petitioned to consider and enter the accompanying Information Disclosure Statement.

F: WP50 USERS ATTY TAM AUGUSTIN 1342-119.PET

The petition fee set forth in 37 CFR 1.17(i) is satisfied by the accompanying check in the amount of \$130. Authorization is hereby given to charge any deficiency to Deposit Account No. 02-0460. This paper is submitted in duplicate.

Respectfully submitted,

TERRANCE A. MEADOR Reg. No. 30,298

BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 B Street, Suite 3100 San Diego, California 92101

Telephone (619) 233-9004



#### UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

Address: Box ISSUE FEE
ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

## NOTICE OF ALLOWANCE AND ISSUE FEE DUE

RECEIVED

F3M1/0203

FEB 07 1997

TERRANCE A MEADOR BAKER MAXHAM JESTER & MEADOR SYMPHONY TOWERS 750 P STREET SUITE 2770 SAN DIEGO CA 92101

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUI	P ART UNIT	DATE MAILED
08/019.719	04710795	010	GRAHAM, M	33,04	02703787
First Named					
Applicant △itimitina Tinid	F.	SEAT	T D. 1		

WENTION INFLATABLE LOWER BODY THERMAL BLANKET

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY.	FEE DUE .	DATE DUE
ı						
Jan 1347-114	607-107	. ()()()	JIA UTIL	LAA NEE	\$645,80	100.70 F 475

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

'HE ISSUE FEE MUST BE PAID WITHIN <u>THREE MONTHS</u> FROM THE MAILING DATE OF THIS NOTICE OR THIS NPPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

#### 10W TO RESPOND TO THIS NOTICE:

Review the SMALL ENTITY status shown above. If the SMALL ENTITY is shown as yes, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown

If the SMALL ENTITY is shown as NO: ,

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.
- I. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "6b" of Part B should be completed.
- II. All communications regarding this application must give application number and batch number. Please direct all communication prior to issuance to Box ISSUE FEE unless advised to the contrary.

MPORTANT REMINDER: Patents Issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely paying it print fees when due.

TOL-85 (REV. 05-96)(0651-0033)

2, YOUR COPY

#### Notice of Allowability

Application No. 08/419,719 Applicant(s)

Augustine et al.

Mark S. Graham

Group Art Unit 3304



All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course. ∑ This communication is responsive to amendment B filed 11/4/96 The allowed claim(s) is/are 26-35 ☐ The drawings filed on \_\_\_\_ \_\_\_\_\_ are acceptable. Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received in Application No. (Series Code/Serial Number) ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)). \*Certified copies not received: Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED. X Applicant MUST submit NEW FORMAL DRAWINGS  $\square$  because the originally filed drawings were declared by applicant to be informal. 🖾 including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. 3 . including changes required by the proposed drawing correction filed on approved by the examiner. including changes required by the attached Examiner's Amendment/Comment. Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal lettter addressed to the Official Draftsperson. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included. Attachment(s) ☐ Notice of References Cited, PTO-892 ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Notice of Informal Patent Application, PTO-152 ☐ Interview Summary, PTO-413 Examiner's Comment Regarding Requirement for Deposit of Biological Material □ Examiner's Statement of Reasons for Allowance ENT'D FEB 0 7 1997

-2-

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In claim 28, line 2, "the" (first occurrence) has been replaced with --a-- to correct an antecedent basis problem.

Any inquiry concerning this communication should be directed to Mark S. Graham at telephone number (703) 308-1355.

MSG

23 January 1997

MARKS GRAHAM MARKS GRAHINER DRIMARY EXAMINER

							SHEET	_1 OF _
rm PTO-14				Docket No. 134	2-119	Application I	No. 08/419,7	9
•	VFORMATION DISCLOS IN AN APPLICA		N	Applicant: S.D.	Augustine et al		· · · · · · · · · · · · · · · · · · ·	
NO.	(Use Several Sheets If			Filing Date: Apr	il 10, 1995	Group Art Ur	nit 3304	
J70)	95 <u>/</u>		U.S. PATEN	DOCUMENTS				
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	100000000000000000000000000000000000000							
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	DOGULAÇIY NUMBER	2175		NINT DV	CLASS	CUPOL ACO	TRANSLATION	
	DOCUMENT NUMBER	DATE	Li Ci	COUNTRY		SUBCLASS	YES	NO
-								
			OTHER DOCU	MENTS (Including	Author, Title	Date, Pertinen	t Pages, Etc.	)
12	Deposition of Ran District of Missou			edical, Inc. v. Augu , 1996	stine Medical,	Inc., Case No. 4:5	95CV00514 L	OD, Eastern
i.	Photograph Exhibi	t No. 1 of Depos	sition of Randal	C. Arnold				
11-	Photograph Exhibi	t No. 2 of Depos	sition of Randal	C. Arnold				
·6-	Photograph Exhibi	t No. 3 of Depos	sition of Randal	C. Arnold				
16	"Normothermia In	The O.R.", Exhib	oit No. 4 of De	osition of Randal (	C. Arnold			

EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

DATE CONSIDERED /

(2/92 PTO)

**EXAMINER** 

The O.I.ASN date stamp 1167 8011 acviinmtenges

SUPPLEMENTAL I INFORMATION DISCLOSURE STATEMENT 4 for "Thermal

Applicant:
Assignee:
Serial No.:
Filed: S.D. Augustine et al Augustine Medical, l 08/419,719 t al . Inc.

and the second second

April 10, 1995

Enclosures: PTO form 1449 & 10 a check for \$230.00 cited

references

Mailed: January 24, 1997

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STATEMENT for "Thermal

The USPTO

date

Applicant:
Assignee:
Serial No.:
Filed: SUPPLEMENTAL INFORMATION DISCLOSURE Blanket" (3 pgs.) S.D. Augustine et al Augustine Medical, Inc. AN ROOM

Enclosures: PTO form 1449 & 10 cited a check for \$230.00 April 10, 1995

08/419,719

Mailed: January 24, 1997

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A PROFESSIONAL LAW CORPORATION
SYMPHONY TOWERS (619) 233-9004
750 B STREET SUITE 3100 SAN DIEGO, CA 92101 PENINSULA BANK OF SAN DIEGO SAN DIEGO, CA 92103 90-3482-1222 01/24/97 16886 \*\*\*\*\*\$230.00 DATE **AMOUNT** \*TWO HUNDRED THIRTY AND 00/100 DOLLARS\* ΓHE FER U.S.P.T.O. GENERAL ACCOUNT

"Olsass" (122234822): 820266401

"PATENT"

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applica	tion of:	)	
S.D. AUGUS	TINE ET AL.	)	Group No. 3304
Serial No.:	08/419,719	)	
Filed:	April 10, 1995	)	Examiner: S. Graham
For:	THERMAI BLANKET	)	

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

#### CERTIFICATE OF MAILING 37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date below:

1/24/97 Terrance & Mead

#### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In satisfaction of their duty of candor and fair dealing, the applicants hereby cite the documents listed on the accompanying Form PTO-1449 with respect to the above-identified patent application under the provisions of 37 CFR, 1.97(C) and 1.17(A). The filing of this Information Disclosure Statement should not be construed to mean that a search was conducted or that no other material information, as defined by 37 CFR 1.56, exists. The Examiner is respectfully requested to make of record this information if deemed relevant to the examination of this application.

WPSC USERS ATTY TAM AUGUSTIN 1342-119,ID

ļ

In addition, disclosure is made of the following litigation matters in which U.S. Patent No. 5.405.371 is involved:

- Augustine Medical, Inc., Plaintiff v. Mallinckrodt Group, Inc. and Mallinckrodt Medical, Inc., Defendants, Civ. No. 4-94-CIV-875, U.S. District Court, District of Minnesota, Fourth Division;
- Mallinckrodt Medical, Inc., Plaintiff v. Augustine Medical, Inc., Defendant, Civ. No. 4-95-CIV-1145 (formerly Case No. 4:95CV00514LOD), U.S. District Court, District of Minnesota, Fourth Division;
- 3. <u>Augustine Medical, Inc., Plaintiff v. Gavmar Industries, Inc., Defendant, Civ. No.</u> 4-94-CIV-888, U.S. District Court, District of Minnesota, Fourth Division;
- Augustine Medical, Inc., Plaintiff v. Medisearch P.R., Inc., Baxter Healthcare Corporation, Baxter International Inc., and John K. Whitney Sr., Defendants, Civ. No. 4-96-347, U.S. District Court, District of Minnesota, Fourth Division;
- 5. Augustine Medical, Inc., Plaintiff v. Progressive Dynamics, Inc., Eugene Kilbourn.
  Robert Crozier, Blue Ridge Anesthesia & Critical Care, Inc., Brett Smith, Steven
  Morris, Keomed, Inc., Desmond Keogh, Central Medical, Inc. and Dennis Mills,
  Defendants, Civ. No. 4-96-CV-345, U.S. District Court, District of Minnesota,
  Fourth Division;
- Augustine Medical. Inc., Plaintiff. v. Respiratory Support Products. Inc., Smiths Industries. Inc. (USA). Smiths Industries Medical Systems and Smiths Industries PLC. Defendants, Civ. No. 4-96-CIV-346, U.S. District Court, District of Minnesota, Fourth Division:
- Augustine Medical. Inc., Plaintiff v. Cincinnati Sub-Zero Products. Inc., Leonard D. Berke and Steven J. Berke, Defendants, Civ. No. 4-95-CIV-637, U.S. District Court, District of Minnesota, Fourth Division; and
- Seabrook Medical Systems. Inc., Plaintiff, v. Augustine Medical, Inc., Defendant, Civ. No. C-1-95-1149, U.S. District Court. Southern District of Ohio, Western Division.

Matter No. 2 (Mallinckrodt v. Augustine) has been moved from the Eastern District of Missouri to the District of Minnesota. Fourth Division. Matters No. 2-7 have been consolidated with Matter No. 1 for discovery.

Document A, the Deposition of Randall C. Arnold (a coinventor of the '371 patent and this application), was taken in Matter No. 2, before consolidation with Matter No. 1. Documents B-E are exhibits in Document A.

Document F, the defendant's memorandum for partial summary judgment in Matter No. 1, is referenced in the accompanying Statement by Attorney Under 37 CFR 1.175(b).

Document G, a report and recommendation by Magistrate Franklin L. Noel in Matter No. 1, includes findings to the effect that Claims 1, 3, 4 and 8 of the '371 patent are invalid under 35 U.S.C. 102(b). Documents H, I and J are memoranda related to Document G.

Activity that raised the issue discussed in Document G occurred at the Annual Meeting of the American Society of Anesthesiologists in October, 1989. This activity is described in Document A, beginning at page 85.

A check in the amount of \$230 is enclosed in accordance with § 1.97(c)) is enclosed. Please charge or credit Deposit Account 02-0460 any discrepancy. A duplicate of this paper is enclosed.

Respectfully submitted,

TERRANCE A. MEADOR Attorney for Applicant(s)

Turancel. head

Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 "B" Street, Suite 3100 San Diego, California 92101

Telephone: (619) 233-9004

"PATENT"

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applica	ntion of:	)	
S.D. AUGUS	STINE ET AL.	)	Group No. 3304
Serial No.:	08/419,719	)	
Filed:	April 10, 1995	)	Examiner: S. Graham
For:	THERMAL BLANKET	)	

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

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- Augustine Medical, Inc., Plaintiff v. Mallinckrodt Group, Inc. and Mallinckrodt Medical, Inc., Defendants, Civ. No. 4-94-CIV-875, U.S. District Court, District of Minnesota, Fourth Division;
- Mallinckrodt Medical, Inc., Plaintiff v. Augustine Medical, Inc., Defendant, Civ. No. 4-95-CIV-1145 (formerly Case No. 4:95CV00514LOD), U.S. District Court, District of Minnesota, Fourth Division;
- 3. <u>Augustine Medical, Inc., Plaintiff v. Gaymar Industries. Inc., Defendant, Civ. No.</u> 4-94-CIV-888, U.S. District Court, District of Minnesota, Fourth Division:
- Augustine Medical, Inc., Plaintiff v. Medisearch P.R., Inc., Baxter Healthcare Corporation, Baxter International Inc., and John K. Whitney Sr., Defendants, Civ. No. 4-96-347, U.S. District Court, District of Minnesota, Fourth Division;
- Augustine Medical, Inc., Plaintiff v. Progressive Dynamics, Inc., Eugene Kilbourn.
   Robert Crozier, Blue Ridge Anesthesia & Critical Care, Inc., Brett Smith, Steven
   Morris, Keomed, Inc., Desmond Keogh, Central Medical, Inc., and Dennis Mills.
   Defendants, Civ. No. 4-96-CV-345, U.S. District Court, District of Minnesota,
   Fourth Division;
- Augustine Medical, Inc., Plaintiff, v. Respiratory Support Products, Inc., Smiths Industries, Inc. (USA), Smiths Industries Medical Systems and Smiths Industries PLC, Defendants, Civ. No. 4-96-CIV-346, U.S. District Court, District of Minnesota, Fourth Division;
- Augustine Medical, Inc., Plaintiff v. Cincinnati Sub-Zero Products, Inc., Leonard D. Berke and Steven J. Berke, Defendants, Civ. No. 4-95-CIV-637, U.S. District Court, District of Minnesota, Fourth Division; and
- 8. <u>Seabrook Medical Systems. Inc.. Plaintiff, v. Augustine Medical, Inc.. Defendant, Civ. No. C-1-95-1149, U.S. District Court, Southern District of Ohio, Western Division.</u>

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A check in the amount of \$230 is enclosed in accordance with § 1.97(c)) is enclosed. Please charge or credit Deposit Account 02-0460 any discrepancy. A duplicate of this paper is enclosed.

Respectfully submitted,

TERRANCE A. MEADOR Attorney for Applicant(s)

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Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 "B" Street, Suite 3100 San Diego, California 92101

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Docket No. 1342-119 Application No. 08/419,719 ırm PTO-1449 INFORMATION DISCLOSURE CITATION Applicant: S.D. Augustine et al IN AN APPLICATION (Use Several Sheets If Necessary) Filing Date: 04/10/95 Group Art Unit 3304 U.S. PATENT DOCUMENTS FILING DATE XAMINER IF APPROPRIATE NAME SUBCLASS DOCUMENT NUMBER DATE CLASS INITIAL FOREIGN PATENT DOCUMENTS TRANSLATION DOCUMENT NUMBER DATE COUNTRY CLASS SUBCLASS OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Deposition of Randall C. Arnold in Mallinckrodt Medical, Inc. v. Augustine Medical, Inc., Case No. 4:95CV00514 LOD, Eastern District of Missouri, Eastern Division, February 27, 1996. В Photograph Exhibit No. 1 of Deposition of Randall C. Arnold C Photograph Exhibit No. 2 of Deposition of Randall C. Arnold D Photograph Exhibit No. 3 of Deposition of Randall C. Arnold "Normothermia In The O.R.", Exhibit No. 4 of Deposition of Randall C. Arnold ξ Memorandum In Support Of Defendant's Motion For Partial Summary Judgement Of Non-Infringement in Augustine Medical, Inc., Plaintiff v. Mallinckrodt Group, Inc. and Mallinckrodt Medical, Inc., Defendants, Case No. 4-94-875, United States District Court. District of Minnesota, Fourth Division. pp. 19-25. G Report and Recommendation of magistrate Judge Franklin L. Noel in Augustine Medical, Inc., Plaintiff v. Mallinckrodt Group. Inc. and Mallinckrodt Medical, Inc., Defendants, Case No. 4-94-875, United States District Court, District of Minnesota, Fourth Division, pp. 1-19. Memorandum In Support of Defendants' Motion For Partial Summary Judgment, Augustine Medical, Inc., Plaintiff v. Mallinckroesi Group, Inc. and Mallinckrodt Medical, Inc., Defendants, Case No. 4-94-CV-875, U.S. District Court, District of Minnesota, Fourtis

Mallinckrodt Medical, Inc., Defendants, Case No 4-94-CV-875, U.S. District Court, District of Minnesota, Fourth Division. EXAMINER DATE CONSIDERED

Inc., Defendants, Case No 4-94-CV-875, U.S. District Court, District of Minnesota, Fourth Division.

Memorandum of Augustine Medical, Inc., Augustine Medical, Inc., Plaintiff v. Mallinckrodt Group, Inc. and Mallinckrodt Medical.

Defendants' Reply To Memorandum Of Augustine Medical, Inc., Augustine Medical, Inc., Plaintiff v. Mallinckrodt Group, Inc. and

EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

(2:92 PTO:

Division.

Kirby A. Kennedy & Associates (612)922-1955

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Page 1 - Page

With regards to?

Condenselt™ Randy Arnold Page 7 A. Dr. Augustine, I think, seemed to feel that in 2 a majority of cases that the anesthesiologist would probably 3 end up using a -- a card on the left-hand side, but that there might be certain instances where a clinician would 5 prefer putting the -- the hose and the machine on the 6 right-hand side. Q. What instances would those be, did you discuss 8 that? A. I guess just a preference for, you know, how cluttered the O.R. was and whether there was room for 10 additional equipment on the left side. Q. Did you discuss the advisability of having a single nozzle entry versus two nozzle entries? A. I'm sure we did. Q. 15 Do you recall what you discussed in that 16 regard? 17 Not particularly, no. 18 How about generally? Do you remember any general - anything general about any discussions that you've 20 had with Dr. Augustine during the summer of 1989 regarding 21 one nozzle entry versus two nozzle entries? A. Not specifically, no, I don't. 23 Q. Did you retain the photographs that you looked 24 at or pictures that you looked at regarding the O.R. room 25 layout? Page 8 A. I don't believe so. Q. Did you keep a file of your early design work 2 in 1989? A. I did not. 5 Q. Did you during that development process of the summer of 1989 did you make any drawings or notes? A. I'm sure I did. What did you do with the drawings and notes? Probably threw them away long ago. O. Do you recall throwing them away?

A. Not specifically.

15

16

17

Q. Did you look for those drawings and notes in 11 connection with production of documents in connection with the lawnite?

A. Yes. Q. And were you able to find any?

A. No.

Q. Did you sketch any pictures of an O.R. room

18 19 layout yourself?

20 A. I couldn't say for certain.

Q. Did Dr. Augustine sketch any pictures of an

22 O.R. room laryout?

A. I don't recall. 24

Q. You indicated that you had discussions about how your product would interface with patients. Do you

Page 5 Q. With regards to designing the O.R. line of 2 products. Did be give you parameters or guidance in any way? A. I believe he did. O. Do you recall what that was? A. A basic description I think he gave me of the 6 operating room layout and how our product would need to interface with - with patients. Q. Do you recall what he told you about the basic description of the O.R. room layout? 10 A. We talked about operating room tables, gas 11 machines where they're placed, other types of equipment that 12 might be present in the O.R. Q. Did he show you any pictures or photographs? A. Yes. 14 115 Q. Did you actually visit any hospital O.R. rooms 16 to acquaint yourself with the layout? 17 A. I don't recall 118 Q. But you do recall seeing pictures? A. You. 20 Q. Do you recall whether Dr. Augustine pointed 21 out that it would be favorable to have a - strike that. Do 22 you recall any discussions regarding which side of the 23 operating room table would be a more appropriate side for the 24 blower to be placed? A. Yes. Q. And this is during the summer of 1989? A. I believe so 2 Q. What was your discussions in that regard? A. I believe Dr. Augustine told me that the --5 the gas machine was typically placed on the 6 anesthesiologist's right side and that that side was 7 generally quite cluttered with equipment. And we felt that - or he felt that the -- probably the best place to put our piece of equipment would be on the - on the left-hand side. Q. Is there - did you go - did you, in fact, go 11 about designing the O.R. blankets with the thought in mind

12 that the equipment would be placed on the left side?

Q. That wasn't a consideration at all in your

Q. Did you decide to do anything with respect to

A. Well, we discussed which side we should put

Q. And what was your discussions about which side

A. We certainly had discussions about it.

18 the design of the blanket in view of those discussions that

19 the right side of the operating room table was cluttered?

Q. And this is in the summer of 1989?

21 the -- the -- the entrance card on for our blanket.

A. I think we - we left it open.

15 design, in your design work?

Page 5 - Page 8

A. Yes

to put the entrance card on?

13

14

23

Condenseit Randy Arnold Page 9 1 able to gain enough surface area there to effectively 1 recall what those discussions were? 2 maintain normothermia. A. I believe we talked about some of the - the O. Did Dr. Augustine show you photographs or 3 primary positions that - that patients were in for varying 4 illustrations of these various types of positions that 4 types of surgeries and how the - we thought that our - our 5 patients would be in for surgery? 5 product might interface with - with the patient and the I believe he did. 6 surgeon. Q. And again, what were the specific types of Q. What do you mean by how your product would 8 positions that patients were in for surgery that you interface with the patient and the surgeon? 9 discussed? A. Well, we were trying to basically pioneer a -MS. SORANNO: Objection, asked and - a new product and come in with something that hadn't 10 10 11 answered. 11 been done before. And we - we didn't want to place a piece 12 BY MR. KURZ: 12 of equipment or a product on the patient or in the way of the Q. Well, the first thing you said was abdominal 13 surgeon that would give them a negative first impression of 14 cases. Do you recall saying abdominal cases a few minutes 14 our product. So we were somewhat concerned with designing a 15 — a system which would effectively warm the patient but not 15 ago? A. I recall that. 16 16 inverfere with - with the other goings on of - of the Q. In abdominal cases do you recall how -- the 17 operating room. 18 position that Dr. Augustine showed you patients were in for Q. Prior to the summer of 1989 you didn't have abdominal cases? 19 any experience with respect to designing products for the A. I don't recall specifically, no. 20 medical profession did you? Q. How about upper chest cases, do you recall A. I don't believe so. 21 22 what position Dr. Augustine showed you patients were in for Q. When you say you were pioneering a new upper chest cases? 23 product, something that hadn't been done before, what were A. I don't specifically recall, no. 24 24 you referring to? Q. But you recall that patients -- do you recall A. Convectively warming patients Page 12 Page 10 1 seeing pictures of patients with their arms outstretched on 1 intraoocratively. an armboard? Q. Were you familiar with any other methods of A. I believe so. warming patients other than convective warming with respect Q. Do you recall seeing any pictures where to the operating room? patients were lying with their arms next to their bodies? Water mattress technology. A. I believe so. Anything clse? Q. Was there a decision during the summer of '89 A. Not that I can recall. to attempt to design a convective warming blanket that woul Q. When did you first become aware of water warm patients when they were in surgery with their arms mattress technology? stretched out on armboards? A. When I started working with Augustine Medical. 10 A. Can you repeat that question? Q. How did you learn about water mattress 11 MR. KURZ: Could you read it back, please? 12 12 technology while working at Augustine Medical? (Whereupon, at this time the requested A. Through discussions probably with 13 portion of the record was read back by 14 Dr. Augustine and looking at literature. the Court Reporter.) Q. You mentioned that you discussed the primary 15 A. I believe so. 16 position patients were in for varying types of surgeries. BY MR. KURZ: 17

What types of positions did you discuss?

A. We discussed positions where or situations 19 where we thought that we could let's say interface with our product effectively and be able to - to warm the patient. 21 So we talked about like your basic abdominal cases where --22 or upper chest cases where we wouldn't have a lot of space 23 and might be able to use either a, you know, a lower body

24 blanket to - to warm the feet or legs or be able to position 25 the patient with their arms outstretched on armboards and be Kirby A. Kennedy & Associates (612)922-1955

20

Q. Was there a decision during the summer of 1989 19 to attempt to design a convective warming blanket to warm patients when their arms were next to their bodies as oppose to stretched out?

A I believe so.

Q. And what was the blanket design that --24 generally that was decided upon in that second instance?

The lower body surgical blanket.

Page 9 - Page 1

Depo-Squish Con	Page 15
1 450	13 Q. Do you recall approximately? Would it be once
1 Q. Were there any other basic blanket designs	among a month?
2 that were decided to be developed during the summer of '89	2 a day, once a week, once a month. 3 A. I'm not for certain. I think be could have
3 aside from the arms stretched out upper body and the lower	A. I'm not for certain. I think the could take
	4 still been residing in Kansas City at that time and, I think,
4 body?	5 coming up to the Twin Cities like every other week or
5 A. I think we decided that we could if we had	I'm not for certain. I know at that time, you
6 those two blankets for those two situations we could	if I had a question I would track him down.
7 basically have enough of a product line to launch.	The you primarily responsible with coming up
8 Q. Were any other designs discussed?	it among of different blanket designs to meet the
a A I don't recall.	l l l l l l l l l l l l l l l l l l l
10 Q. Do you recall discussing a arms to the side	10 desire to create an upper over)
11 upper body blanket design?	the Name on
t don't recall	the desired come un with prototypes and then
and work with you during the summer	of 13 Q. And you would come up will prove you
h at a blanker decions?	11.
1 11 11 11 1 1 1 1 1 1 1 1 1 1 1 1 1 1	15 A. Yes. 16 Q. And you came up with the basic design layout
Property of the state of the st	16 Q. And you came up with the with their arms
16 Q. Who helped you?	16 Q. And you can't up had 17 of a upper body blanket to cover a patient with their arms
17 A. I don't recall for certain. 18 Q. Who was in the what was your title at that	18 stretched out?
18 Q. Who was in the " what was you the	19 A. Dr. Augustine and I, yes.
19 time?	20 Q. Together?
20 A. I don't know that I had a title.	21 A. Yes.
21 Q. What did you think you were?	22 Q. Do you recall who came up with the first
22 A. I was the - outside of Dr. Augustine I was	23 sketch of a blanket of that type?
2) the - the R & D employee.	l tabana
1. Street there any other R & D employees?	O Do you recall whether there was a sacreti price
25 A. Scott's dad and — and another fellow named	Page 10
Pa	ge 14 in 1 to building prototypes?
1 Dave Sorvig worked to build manufacturing machinery for us	
a B & D conscity	The same most what the first prototype toolton
not be coming uport on blankes design at all/	Q. Do you recall what the first process with their arms     like for use in connection with a patient with their arms
3 Q. Did Dave sorvig work on annual and 4 A. I don't believe so.	4 like for use in connection will a
n hierarchien?	5 stretched out?
to time.	6 A. I do not. 7 Q. Even a rough idea of what it looked like?
the symmetral 1989?	7 Q. Even a rough ties of water in
1 19	8 A. I couldn't say for certain. 9 Q. Do you recall whether snyone in marketing had
8 A. I don't recall. 9 Q. Can you think of who else might have helped	9 Q. Do you recall whether anyour in the
9 Q. Can you think of who east interest and?	10 eny input in to the design of the O.R. blankets?
10 you during the summer of 1989 saids from Scott's dad?	II A. I don't recall.
11 A. Dr. Augustine himself.	12 Q. How about sales, do you recall meeting or
12 Q. Anyone cise?	12 Q. How about sales at 13 discussing O.R. blanket designs with anyone from sales at
13 A. Are you talking about the specific design or	
14 are you talking about, you know, just working on fabricating	g 14 Augustine?
15 blankets?	16 '89?
16 Q. Working on fabricating blankers.	17 MR. KURZ: The summer of '89.
17 A. I probably had some help from line workers	18 A. I don't recall.
18 within the plant to build prosotypes.	
19 Q. Do you recall any of their name?	it have long it took VOU ITUIN the
on A Idon't	20 Q. Do you recall now using a comment of the first time you started the project to the development of the first
21 Q. Did anyone else work on bianicet design?	
an A I don't recall.	
21 O How often would you mest with Scott Augustus	- I - neder hour long. & day, & work,
24 during the summer of '89 to work on blanket design?	
a a a a B annifically	Z5 month?  Kirby A. Kennedy & Associates (612)922-1955
	Kirby A. Kennedy & Albertain
Page 13 - Page 16	•

R <sub>2</sub>	indy Arnold Condo	n se	II.
Г	Page 17		Depo-Squist
1	A. Things happened really fast, I would guess a	ı	upper body design?
2	day or two probably.	2	A. Through discussions with Dr. Augustine and
3	Q Do you recall how many prototypes you made	)	looking at our existing blankers and our rechnology and
4	during the summer of - approximately how many prototypes you	4	ability to produce blankets and started prototyping blankets.
5	made during the summer of 1989 in connection with the	5	I guess.
6	development of the O.R. blankets?	6	Q. Do you remember what the early prototypes
7	A. I do not.	7	looked like? Could you sketch out for me what your first
8	Q. Would it have been closer to ten or closer to	8	prototype that you remember looked like?
9	a hundred?	9	A. I just don't recall.
10	<ol> <li>It would be closer to a hundred.</li> </ol>	10	Q. Do you recall considering the - strike that,
111	Q. What did you do with the prototypes that you	11	Do you recall looking at the design of surgical drapes with
12	had come up with? Did you store them someplace?	12	respect to the your design of the upper body arms
13	A. Initially for a time I think we probably did.	13	stretched out blanket?
14	Q. Where did you store them?	14	A. I remember discussing draping procedures. I
15	A. In my work area.	15	don't know if we looked at particular designs.
16	Q. Do you know what happened to those prototypes?	16	Q. Do you recall considering - do you recall
17	A. Probably thrown out.	17	considering whether there should be cut-out portions at the
18	Q. Do you know that they were thrown out?	18	head and abdomen in your upper body blanket during the summer
19	A. I would guess so. I haven't seen them in	19	of 1989?
20	years.	20	A. I'm certain that we did at some point.
21	Q. Have you looked for them?	21	Q. At some point did you decide that it would be
22	A. No. I've cleaned out the R & D area and moved	22	appropriate to include cut-out portions around the neck and
23	a number of times and I've never seen them, so I would guess	23	abdomen?
24	that they're nowhere - nowhere around.	24	A. I believe so,
25	Q. I'm sorry?	25	Q. And why did you determine that it was
1	Page 18		Page 21
1	<ol> <li>I would guess that they're nowhere around.</li> </ol>	1	appropriate to include a cut-out portion for the for the
2	Q. Have you undertaken a search for them?	2	neck?
3	A. Not specifically, no.	3	A. Dr. Augustine and I discussed the
4	<ol> <li>With respect to the lower body O.R. blanket do</li> </ol>	4	anesthesiologist's needs in terms of monitoring the patient
5	you recall how the basic shape was determined, how you	5	and the ability to monitor breathing circuits and - and
6	decided on a basic shape?	6	other equipment, and felt that we needed unobscured or at
7	<ul> <li>A. I believe we were looking for a blanket to</li> </ul>	7	least visually to be able to see the patient at all times.
8	cover the lower extremities of the patient, and we felt that	8	So rather than covering their head with a a blanket,
9	a a slight variation on our full body FACU blanket would	9	though it might have warmed the patient very well, it would
10	suffice in this situation.	10	have obscured the anesthesiologist's view.
11	Q. Did you look at any designs of surgical drapes	11	Q. Anything else?
12	to assist in your consideration of appropriate shapes for	12	A. Not that I recall.
13	lower body blanket designs?	13	Q. How about the cut-out portion for the abdomen.
14	A. I don't recall.	14	do you recall why you thought it was appropriate to include
15	Q. Do you ever recall seeing any drawings or	15	cut-out portion for the abdomen?
16	pictures of surgical drapes?	16	A. It's to keep the blanket out of the surgical
17	<ul> <li>A. I remember discussing draping procedures.</li> </ul>	17	field, to give a means for adhering the blanket to the - to
81	Q. With Dr. Augustine?	18	the patient, and preventing the migration of air into the
19	A. Yes.	19	surgical field.
20	Q. During the summer of 1989?	20	Q. That's what the cut-out portion did?
21	A. Yes.	21	A. Well, that's what's occurring at that portion
22	Q. Do you recall what you discussed with respect	22	on the blanket where it attaches. I mean, the cut-out
23	to draping procedures?	23	portion also facilitates the the extremities of that
24	A. I do not.	24	particular blanket to drape down and tuck along the the
		)	

		$\overline{}$	Randy Arne
	Page 2	1	Page
1	<ol> <li>Q. Does the neck cut-out portion also facilitate</li> </ol>	1	the blanket in the summer of '89?
2	2 that draping and attachment to the armboards?	2	A. I don't recall.
3	J. A. Yes.	3	Q. Do you recall the results of any discussions
4	4. If you didn't have the cut-out portions the	4	with surgeons as to - do you recall seeing any results of
5	5 blanket would bunch up and wouldn't conform to the body	){ s	any discussions with surgeons as to the appropriate place to
6	6 the patient, isn't that right?	6	put the nozzle entrance on the upper body blanker?
7	bid. Golden O. Objection, Carls for	7	A. I don't recall.
8	•	8	Q. Do you recall arriving at what we'll call a
9	· · · · · · · · · · · · · · · · · · ·	9	finalized prototype of an upper and lower body blanket during
10		10	the summer of 1989?
11	4. The one of the constant attoris thought,	11	<ol> <li>I would guess it probably stretched more into</li> </ol>
12	on the particular wouldn't back	12	the fall of '89.
13	•	13	Q. Do you know how far into the fall?
14	, o quantities	14	A. I couldn't say for sure.
15		15	<ol> <li>Q. During the fall of – either the summer or the</li> </ol>
16	5 facilitated draping and and adhering to the armboards?	16	fall of '89 did you do any work on redesigning the nozzle
7	A. It's narrower in the portion where it crosses	17	entrance itself?
8	the - the patient and then it's wider on - on either end,	81	A. I don't recail.
9	and those portions are able to tuck around the armboard. If	19	Q. To your knowledge is the nozzle entrance that
0	it was full width the whole way it would have - on the one	20	was incorporated into the finalized prototypes of the upper
1	side it would protrude down in to the surgical field, it	21	and lower body blankets the same?
2	would cover up the the patient's head and and prohibit	22	A. I'm not following your question.
3	the the anesthesiologist from monitoring the patient's	23	Q. Was the nozzle in the finalized prototypes of
4	vital signs.	24	the upper and lower body blankets that you completed in the
5	Q. Did did any of your design work include	25	fall of 1989 was the basic design of the nozzle entrance in
	Page 2	2	Page
i	design of the nozzle entrance openings on the blankets?	1	those two blankets the same?
2	A. I believe so.	1 2	A. I believe so.
3	Q. When you arrived at Augustine, Augustine	,	Q. Was that design essentially the same as the
4		4	PACU blankets that had previously been sold?
5	with the PACU blankets, isn't that right?	1 5	A. I believe so.
6	A. Yes, they did.	6	Q. And can you can you sketch out for me what
7	Q. Did you redesign that nozzle entrance in	7	that nozzle design looked like?
8	connection with the O.R. blankets?	8	MS. SORANNO: What time frame?
,	A. I don't recall.	9	MR. KURZ: The one that was incorporated
)	Q. What work do you recall doing on nozzle	10	in the finalized prototypes in the fall of 1989, which the
1	entrances during the summer of '897	lii.	witness testified were the same as the previous PACU
2	A. Just in regards to the blankets we were	1	blankets.
,	working on developing I think we just talked about placement		THE WITNESS: He's talking about the card
	and - and where they belonged and whether there should be	14	that goes on the
	one or two on the upper body cover.	15	MR KURZ: That's correct.
,	Q. Did you consider whether there should be one	16	
	or two on the lower body cover?	17	MS. SORANNO: Counsel, when you say
,	A. I don't recall.	18	"prototype" what do you mean?
,	Q. Do you recall doing any design work on the	19	MR. KURZ: Well, if you have an objection,
	entrance itself on the design of the cardboard portion?	20	make it. The witness understood what I was talking about
		1	BY MR. KURZ:
		21	Q. Do you understand what I said when I said
	Q. In the summer of '89,	22	finalized prototypes? What did you have in your mind w
	A. I don't believe so.	23	you answered my questions with respect to finalized
	Q. Did you do any work on how the cardboard	24	prototypes?
	portion of the entrance, nozzle entrance would be achieved to	25	<ul> <li>A. Basically the design we came up in prototyping</li> </ul>

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Page 25
                                                                              Do you know who that vendor was?
  and were ready to release to the market.
                                                                         A. I do not.
       Q. And that was in the fall of 1989, right?
                                                                         Q. Do you know who manufactures the bose cards
       A. I believe so.
                                                                     for Augustine today?
               MR. KURZ: Off the record.
                                                                          A. I do not.
               VIDEO TECHNICIAN: Going off video record.
                                                                          Q. Have you ever known the identity of any hose
            (Whereupon, a brief off the record
                                                                     card manufacturer for Augustine?
             discussion was beld.)
                                                                          A. At some point I guess I probably have, but
            (Whereupon, a brief recess was taken
                                                                      I've forgonen.
                                                                          Q. Do you know if Augustine has changed
             from 10:05 to 10:15.)
                                                                  10
                VIDEO TECHNICIAN: Continuing with video
                                                                      manufacturers of bose cards?
10
                                                                  11
                                                                           A. I couldn't say for certain.
11 record.
                                                                  12
                                                                           Q. When these hose cards - when these hose cards
12 BY MR KURZ
        Q. We had been discussing the design of the
                                                                  14 arrived from the manufacturer, I'm talking about the bose
14 nozzle entrance in the finalized prototype of the upper and
                                                                   15 cards that existed up through the fall of 1989, did they come
15 lower body blankets that existed in the fall of 1989. And
                                                                   16 with the bole cut out in the center as is shown in Anderson
16 yesterday during Mr. Anderson's deposition he sketched out
17 the basic form of a nozzle entrance that existed when - when
                                                                   17 Exhibit 57
                                                                            A. I don't recall.
18 he was - when he came to Augustine in 1990, and I'll show
                                                                            Q. The bose cards that you worked with in
 19 you that, and that was marked as Anderson Exhibit 5
                                                                   20 connection with your prototypes that you worked on during the
                                                                   21 summer through the fall of 1989, when you were working on
 20 yesterday. Do you see that?
                                                                   22 those prototypes did you adhere the hose card to the - to
         A. Uh-hum.
          Q. Is that the same basic shape of nozzle
                                                                    23 the blankets?
 23 entrance that -- that you were referring to with respect to
                                                                             A. Probably.
 24 the finalized prototype that existed in the fall of 1989?
                                                                    24
                                                                             Q. You pecked off the back and then adhered them
                                                                    25
                                                                                                                            Page 23
          A. I believe so.
                                                           Page 26
                                                                        to locations on the - on the blankets?
          Q. And can you will me how that was -- how that
                                                                              A. Probably.
  2 was constructed? What was it - what were the materials, how
                                                                              Q. Do you recall whether the hole was already cut
     was it - who manufactured it and how it was manufactured,
                                                                         out when you were -- when you were doing that?
                                                                              A. Before adhering them?
   4 et ceters?
                   MS. SORWAND: Objection, lack of
                                                                              Q. Yes.
                                                                              A. I don't think so, no.
   6 foundation.
           A. I believe it was just a heavy weight cardboard
                                                                                   You don't think the hole was cut out?
   8 substrate with a adhesive backing and a peri-off liner on -
                                                                              Q.
                                                                              A. No.
                                                                              Q. The PACU blankets that were in existence when
      on one side.
                                                                      10
                                                                          you came to the -- to Augustine in 1989 do you recall those
   10 BY MR. KURZ:
           Q. When you say peel-off liner that would be on
                                                                          blankets?
                                                                       12
                                                                               A. To a degree, year
   12 the back side?
                                                                               Q. When those were shipped to customers was the
            A.\ On the back side.
                                                                       15 hole in the hose card already cut out, the cardboard, was the
    13
                 Were these - what would you refer to this as,
   15 the bose card? What do you feel comfortable calling that?
                                                                       16 cardboard removed from the hole?
                                                                                       MS. SORANNO: Objection, lack of
            A. We used to call them flags.
            Q. Flags? Do you understand what I would be
                                                                       18 foundation.
    17
        talking about if I said a bose card?
                                                                                A. I don't recall.
                                                                        19
            A. Yas.
                                                                           BY MR. KURZ:
    19
                                                                       20
                                                                                Q. Do you recall when - when the completed
             Q. But you referred to them as flags?
                                                                       22 blankets were put in packages whether there was cardboard in
    20
             A. Flags or hose cards.
                                                                       23 this hole of the - of the nozzle entrance?
                  Were these manufactured during - up through
        the fall of 1989 were these flags or bose cards manufactured
    22
                                                                                        MS. SORANNO: Objection, lack of
                                                                        24
        for Augustine by an outside vendor?
```

25 foundation.

124

	Randy Arn
Page 1 A. I just don't recall.	Page
2 BY MR. KURZ:	1 A. I don't believe so.
	<ol> <li>Q. So it's now your recollection that there was</li> </ol>
4. The just for the feeting, my references to	3 no cardboard in this round inner circle portion of the bose
4 to "this" have been to Anderson Exhibit 5, do you underst 5 that?	т. Б. С.
	5 A. When I was making prototypes, yea.
	6 Q. Do you recall whether you removed any
. Q. And that s was discussed by Mr. Anderson as	5 7 cardboard from this inner circle or whether they were - they
The state of the s	8 came that way from the manufacture?
o you locall whether is connection with	ith 9 MS. SORANNO: Objection, asked and
0 the PACU blankets that were being sold during the summer	r and 10 answered.
up through the fall of 1989 whether those blankets strike	ce     11 A. I just don't recall.
2 that. Do you recall whether the PACU blankets that were	12 BY MR KURZ:
being sold during the summer and fall of '89 included a ho	
4 card where the blanket material under the hose card had be	ects 14 problems with inserting the hose into the prototypes through
5 cut in any way?  MS SORANNO: Objection last of	15 the bose card when you did not punch the plastic through with
mai soloutivo. Objection, lack of	16 your finger or a knife but rather had the hose punch through
7 foundation.	17 the plastic?
BY MR. KURZ:	18 A. I don't recall.
Q. And when I say when I refer to the blanket	19 Q. You don't recall ever having a problem?
material under the hose card I mean in this entrance way, the	the 20 A. I just don't remember.
circular entrance way, was that cut?	21 Q. Do you remember designing any way to
A. I don't recall,	22 facilitate a customer - strike that. When you arrived at
<ol> <li>So you don't recall whether it was sold with</li> </ol>	23 the finalized prototype how was the hose entrance designed to
the - with plastic covering the entrance way, or whether it	24 be utilized by the customer?
was sold with the plastic cut away, is that right?	25 A. I don't recall specifically.
Page	. 10
MS. SORANNO: Same objection.	Page : 1 Q. Do you recall ever designing any means for
A. I just don't recall.	2 facilitating a customer inserting the hose into the hose card
BY MR. KURZ:	3 and into the blanket?
Q. Now, when you adhered these bose cards to the	4 A. I'm not sure I follow that question.
blankets that you were working on during the summer and fall	5 Q. Do you recall any design considerations that
of 1989 how did you book up the bose to the blanker?	6 went in to your design of the nozzle entrance that would
A. Push the bose nozzle in through the card.	7 facilitate the customer putting the nozzle into the blanket?
Q. Did you have to break - how did you break the	8 A. I don't recall.
plastic?	- 13 1000110000
A. Sometimes the hose end itself would do it,	- 4 - 50 year recent any ansemments you man with
sometimes you would just poke your finger through it. The	The same of the same with the same of the
plastic was very thin.	The second of th
Q. So you wouldn't have so cut the plantic to do	
that?	4. Did and miled come a time in the last of
A. No, not necessarily,	14 1989 when you felt that you had arrived at a design of an
Q. Do you recall taking a knife ever and cutting	15 upper body blanket that was ready for manufacture?
the plastic with a knife?	16 A. I believe so.
A. I might have.	17 Q. Would the same be true of a lower body O.R.
	18 blanket?
t yes and seems you promise and make	19 A. Yes.
directly through the bose card through the plastic without	20 Q. Do you recall when in the fall of 1989?
cutting it?	21 A. I do not.
A. I believe so, yes.	22 Q. Did you attend the New Orleans A.S.A. in 1989?
Q. And when you poked the hose through do you	23 A. I did.
recall whether there was cardboard that you were also pushing through?	24 Q. How many - strike that. Do you attend the

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And when I say "those designs" I mean designs

Q. Was that the designs that were -- were those

designs the designs that were shown at the 1989 show?

Q. Did those designs, in fact, ever go in to

A. Yes.

A. I believe so.

A. I believe so.

IS BY MR. KURZ:

23 production?

Q.

20

21

22

24

Q. It could have been within the last two weeks

A. I don't remember. I just don't remember. I

have seen the pictures before, I just don't know when it wi

the past week was the first time you ever saw these

Q. You don't know whether it was within - within

18 that you first saw these photographs?

A. I just don't recall.

20

23

25 photographs?

Q. Was it within the past week?

Depo-Squish Conder		1130	It <sup>™</sup> Randy Arnold
	Page 37		Page 39
1	MS. SORANNO: Objection, asked and	1	what these are pictures of independent of anything that your
2	answered.	2	counsel has told you?
1	A. That's what I've said basically, yes.	3	A. Well, that's our trade show booth in
4	BY MR. KURZ:	4	New Orleans.
5	Q. Do you know whether the first time you saw	5	Q. And you know that by looking at these?
6	these photographs was within the last three days?	6	A. Well. I built the booth, so.
7	A. I don't know.	7	Q. And this is the 1989 trade show in
8	Q. Do you know whether the first time you saw	8	New Orleans?
9	these photographs was yesterday?	9	A. Yes.
10	A. I don't think I saw them yesterday. I know I	10	Q. And can you identify the blanket that's - the
11	didn't see them yesterday.	11	two blankets that are shown in Exhibit Number 17. Why don't
12	Q. How about the day before yesterday?	12	you start with the one on the left and then go to the one on
13	A. I didn't see them then either.	13	the right, if you can.
14	Q. Okay. But three days ago you're not sure?	14	A. The one on the left is the lower body O.R.
15	<ul> <li>A. Well, three days ago was Saturday, I didn't</li> </ul>	15	surgical blanket and the one on the right is the upper body
16	see them then either.	16	O.R. surgical blanket.
17	MR. KURZ: Why don't we have a discussion	17	Q. Would these be the blankers that we've
18	off the record.	18	referred to as finalized prototypes earlier?
19	VIDEO TECHNICIAN: Going off video record.	19	A. They were the same design as - as the
20	(Whereupon, a brief off the record	20	prototypes.
21	discussion was held.)	21	Q. And do you know whether looking at the blanket
22	VIDEO TECHNICIAN: Returning to video	22	on the right, the upper body blanket I think you identified
23	record.	23	that as?
24	MR. KURZ: I'd like to mark these	24	A. Yes.
25	photographs as exhibits, please.	25	Q. Do you know how many blankets of that design
	Page 38		Page 40
1	(Whereupon, ARNOLD Deposition Exhibit	1	with two ports were produced by Augustine?
2	Numbers 1 - 3 were marked for identification	2	MS. SORANNO: Objection, asked and
3	by the court reporter.)	3	answered.
4	MR. KURZ: Why don't we go off the record	4	A. I do not.
5	again a second.	5	BY MR. KURZ:
6	VIDEO TECHNICIAN: Going off video record.	6	Q. Do you know if it was more than ten?
7	(Whereupon, a brief off the record	7	MS. SORANNO: Asked and answered.
8	discussion was held.)	8	A. I'm certain it was.
9	VIDEO TECHNICIAN: Continuing with video	9	BY MR. KURZ:
10	record.	10	Q. Do you know if it was more than 50?
11	BY MR. KURZ:	11	MS. SORANNO: Asked and answered.
12	<ol> <li>I've just had these three photographs marked.</li> </ol>	12	A. Probably.
13	as deposition exhibits and we've marked them Exhibits 1, 2, 3	13	BY MR. KURZ:
14	of your deposition of today's date. We've had this one with	14	Q. Okay, that's a little bit different answer
15	the gentleman standing in the picture as Exhibit Number 1.	15	•••
16	this one with a picture of a woman off to the left as	16	
17	Exhibit 2, and this one with a woman slightly more towards	17	
18	the center as Exhibit Number 3. Do you recall ever seeing	18	recollection that it was more than 50?
19	these photographs that have been marked as exhibits other	19	MS, SORANINO: Objection, asked and
20	than with your counsel present?	20	answered.
21	A. I don't recall.	21	A. I just don't recall.
22	Q. Do you recall seeing them with your counsel	22	BY MR. KURZ:
23	prosen(?	23	Q. So you're not sure whether it was more than
24	A. I believe so.	24	50?
25	Q. Do you know what these - do you recognize	25	MS. SORANNO: Asked and answered.

<b>.</b>	
Conde	enselt <sup>™</sup> Depo-Squis
andy Arnold Page 41	Page 4.
	1 Q. How do you know it was changed?
A. I don't recall.	2 A. I just seem to have a recollection of it.
Q. How about the lower body blanket do you know	3 Q. But you don't you never this is a
Q. How about the lower body similar to you identified that	4 recollection norwithstanding the fact that you didn't see it
bow many - which is shown on the left, you identified that as the blanket on the left of Exhibit I, do you know how many	5 being changed and didn't change it yourself?
as the blanket on the left of Exhibit 1, do you allow the left of exhibit 1 were	6 A. Well, certainly every day I would guess at the
lower body blankets of the design pictured in Exhibit I were	7 start of the show that fresh product was put out there.
produced?	8 Q. You said you would guess, but you don't know
A. I do not. Q. Do you know if it was more than ten?	9 that do you?
	10 A. I don't know that, no.
A. I would guess so. Q. Do you know if it was more than 50?	11 Q. Was someone in charge of setting up the
	12 product for the show every day?
A. Probably.  Q. Do you know if it was more than a bundred?	13 A. I don't know specifically. I know I had a
and the second has seen	14 hand in setting the the show up every day.
	15 Q. But you don't recall whether you set up the
e a man acquelly sold?	16 fresh product every day do you?
	17 A. I don't recall specifically, no.
7 A. I do not. 8 Q. Do you know if any were ever sold?	18 Q. Who else had a hand in setting up the product
a shimming lack of	19 every day?
	20 A. The people working the booth.
0 foundation.	21 Q. Who else worked the '89 booth?
1 A. I don't knσw.	22 A. Doug Augustine, Sue Dykins, Scott Augustine, I
2 SY MR KURZ: 3 Q. You don't know if any were ever sold?	23 just don't recall beyond that.
to the section demonstrated	24 Q. Do you know whether Bob Vosskuhler was at this
diewihuted to	25 show?
25 Q. Do you know it any were evel distribute. Page	Page 4
	i a I don't recall.
1 customers?	2 Q. Do you recall when Bob Vosskuhler began
2 MS. SORANNO: Objection, lack of	3 working at Augustine?
3 foundation.	4 A. I do not.
4 A. I don't know.	5 Q. Was it after 1989?
5 BY MR. KURZ:	6 MS. SORANNO: Objection, lack of
6 Q. Do you know if any were ever utilized in	7 foundation.
7 clinical trials?	8 A. I don't recall.
8 A. I don't know. 9 Q. How do you know more than ten were produced?	9 BY MIL KURZ:
9 Q. How do you know more than any want to trade	10 Q. Do you recall how many lower body blankers you
10 A. It was just typical that when we went to trade	23 11 bad at the - at the '89 show?
11 shows that we had ample product on hand. And with customer	12 A. I do not.
12 poking at them and looking at the product that we wanted to	d 13 Q. Do you know whether you had more than one?
13 keep our product fresh and - and looking good, so we changed	
14 our - our product - our display product on a regular basis.	15 Q. But you don't know?
15 Q. How often did you change the display - the	Le A I don't know.
16 upper body product during the course of the 1989 show?	17 Q. But you do know that you had more than one
17 A. I couldn't say.	to want body blanket or you don't know that either?
18 Q. Do you know if it was more than twice?	19 MS. SORANNO: Objection, asked and
19 A. Ob. I'm certain.	ii.
20 Q. Was it more than five times?	20 answered.  21 A. I'm just assuming that we would have had.
21 A. I couldn't say.	
22 Q. Did you change the product?	Vott 600 LEDOW WILLIAM
23 A. I don't recall.	and more than one upper body blanket at the snow do you
24 · Q. Did you see it being changed?	24 you and more than sonanno: objection, asked and
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۲	<del>cpo-</del> Squish Cond	_	Elt. Randy Arnold
١.	Page 45	1.	Page 47
Ľ	answered.		Q. Can you think of any differences between the
1		2	is the soot statuted that were sold - strike that. Do you
1	,	3	know when the first lower body O.R. blankets were first sold?
۱ ٔ	Q. Do you see the blower unit shown in Exhibit 1,	4	A. I do not.
1 5	THE THE SHOWN IN EXCEPTION 1.	5	Q. You do know that there - do you have an '-
6	A. I do.	6	understanding that there came a point in time when lower body
?	Q. Did you work on the design of those blower	7	O.R. blankets were first sold to customers?
8		8	A. Well, I would assume so, yes.
9	A. I did.	9	Q. And you have an awareness of -, of the first
10	Q. Are the units shown in Exhibit 1 prototypes or	10	type of O.R. lower body blanket that was sold to customers
11	production models?	11	don't you?
12	A. They were the first machines off the	12	A. I believe so, yes,
13	production.	13	Q. Is that the same design that's shown in
14	Q. Do you know whether any orders were taken for	14	Exhibit 1?
15	the blower units during the 1989 show?	15	A. I believe so.
16	A. I don't know.	16	Q. Are you aware of any changes that were made at
17	Q. Do you know whether any orders were taken for	17	all to the lower body blanket from the design that was shown
18	the lower body blankets during the '89 show?	18	at the '89 show versus the design that was ultimately sold to
19	A. I don't know that either.	19	customers?
20	Q. Do you know whether any orders were taken for	20	A. I don't know for certain.
21	the upper body blankets during the '89 show?	21	Q. Do you know when the first - do you know
22	A. I don't know that	22	approximately when the first blower units of the type shown
23	Q. Was the lower body blanket that's shown in	23	in Exhibit 1 were sold to customers?
24	Exhibit 1 a production model or a prototype?	24	MS. SORANNO: Objection, lack of
25	A. A production model, I believe.	25	foundation.
	Page 46	П	Page 48
ı	Q. How do you know that?	1	A. I do not.
2	A. That was our our final design and I believe	2	BY MR. KURZ:
3	we were producing them.	3	Q. Do you know what year it was in?
4	Q. You say you were producing them?	4	MS. SORANNO: Same objection.
5	A. I believe so.	5	A. I do not.
6	Q. But you don't know whether you produced more	6	BY MR. KURZ:
7	then ten?	7	Q. Do you know what year the first lower body
8	A. I do not.	8	O.R. blankets were sold?
9	Q. How about the upper body blanket was that a	9	MS. SORANNO: Same objection.
10	production model the upper body blanket that's shown in	10	A. I do not.
11	Arnold Exhibit 1 is that a prototype or a production model?	11	MR. KURZ: What objection is that,
12	A. It's a production model, I believe.	1	counsel?
3	Q. How do you know that?	13	MS. SORANNO: Foundation.
14	A. I don't, I just believe that it was.	14	BY MR. KURZ:
15	Q. But you have no basis for that statement?	15	Q. Do you know what year the first upper body
6	A. It's it's the design that that we went		blankets were sold to customers?
	to production with	17	MS. SORANNO: Same objection.
8	Q. Is the the design that's shown the	18	A. I do not
	blanket that's shown as the lower body blanket in Exhibit 1	19	MR. KLTRZ: Could I have the original
	that's a design that was eventually sold to customers wasn't	20	brochure, please?
	it?	1	BY MR. KURZ:
2			
	MS. SORANNO: Objection, lack of foundation.	22	Q. Do you know whether there were any changes as
	· · · · · · · · · · · · · · · · · · ·	23	between the design of the upper body blanket that's shown in
4	A. I believe so, but I don't know.  BY MR. KLTRZ:		Exhibit 1 versus the design that was ultimately sold to
	DI MR. AUE!	1 2 5	customers?

20 brochure at the '89 trade show do you?

A. I just don't recall.

22 Q. And you have no recollection of distributing this brochure at the '89 trade show do you? 23

24 A. I don't recall, no.

Q. Do you know approximately when this brochure

A. It appears to be, otherwise I would guess the blanket would be deflated.

119 Q. Do you recall when you were describing the 20 blanket while it was inflated at the show whether the -21 whether one hose opening remained sealed?

A. I don't recall.

18

23 Q. Do you recall whether there was any scoring or 24 perforations to the plastic within the hose card on the 25 blankets that were shown at the 1989 trade show?

	•				•		
De	epo-Squish Conde		œ]	[t <sup>™</sup>		Randy Amold 4-5	
	Pag	= 53				Page 55	
1	A. I don't recall.			blankets s	o that users would insert the ho	se?	
2	Q. And when I say "within the hose card" I mean	1	!	<b>A</b> .	Well, that I understood that the	y would stick	
,	within the round circular portion of the bose card.	1	}	the hose r	ozzle in to the in to the card.	Ì	
4	A. That's what I took you to mean, yea.	4	ı	Q.	In to the in to the		
5	Q. Did you arrend the trade - do you know how	1 2	5	A.	The hose card, the flag.		
6	many days the 1989 trade show was?	(	-	-	In to the area of the hose card the		
7	A. I don't recall.	7	7	that do	es not have cardboard in it, is th	nat your .	
8	Q. Did you arrend it every day that it was -	1	3	understan	_		
9	that Augustine had a booth?	9	•		The area meant for insertion, y		
10	A. I don't recall.	10		-	And was it intended that they v	vould just break	
m	Q. Did you attend it more than one day?	11	ı	•	by shoving the hose in?		
12	A. I believe so.	13	2		I don't recall.		
13	Q. Do you know how – when you attended it what	1:			How about the lower body blan		
14	did you do at the show?				he plastic that was within the -		
15	<ul> <li>A. I set up the booth before the trade show</li> </ul>	1:			it region of the bose card, the re		
	began, helped with getting the exhibits out in the morning.	10			gion, do you recall whether tha		
17	and spent some time talking with customers who came by who	1			t was intended that the user wo	uld insert the hose	
18	were interested in our product, and I spent some time taking	11	-	and break	the plastic?		
19	in the rest of the trade show exhibits.	11	-	<b>A</b> .	As I recall there was a small X	, a score done	
20	Q. Do you know where you spent most of your time	2			arp knife or.		
21	during the trade show? Was it at the Augustine booth would	2		Q.	Was it actually - did the score		
22	you say?			•	ugh? Was it - was it cut throu	Su or was it last	
23	A. I don't recall.	2		scored?		}	
24	<ol> <li>Do you recall ever designing the entrance</li> </ol>	2		<b>A</b>	I believe it was cut through		
25	opening - strike that. Do you recall ever designing the	2	5	Q.	And is that the same with the		
Г	Pag	ge 54				Page 56	
1	plastic that would appear within the circle of the hose ca	rd			of 1989 the blanket that was be	ing sold by	
2	on the upper body blanket to be scored or perforated?	1	2				
3	A. I don't recall.	- 1	3		I believe so.	11 1	
4	Q. Do you recall seeing the plastic that was in	l i	4	Q.	So when the consumer got the	blanket there	
	that hose card - strike that. Do you recall ever seeing at		5		a hose card with a circular op		
6	plastic within the circular portion of the hose card being		6	-	the plastic, is that your underst	moung?	
7		ļ	7	<b>A</b> .	As I recall.		
8	A. I don't recall. Could I take a break for just	1	8	Q.	With respect to that's with	Leabect to me	
9	a minute and go to the restroom?		9		at was sold in 1989?	İ	
10	Q. Sure.	- 1	0		Yes.		
11	VIDEO TECHNICIAN: Going off video record.		1	Q.	And that's with respect to the	1000 mds show?	
12	(Whereupon, a brief recess was taken	1	12		that was that was shown at the	E 1707 LIBLE NAUW:	
13	from 11:05 to 11:15.)	- 1	13		I believe so.		
14	VIDEO TECHNICIAN: Continuing with video		14		When you you said you	d the other exhibits	
	record.		15	did duri	ng the show was to walk aroun	this as the show?	
16	BY MR. KURZ:		16		recall seeing a Vital Signs exhi	DIT ST CENTER AND M :	
17	Q. With respect to the blanket that - the upper	- 1	17		I don't recall specifically.	an ambibie?	
18	body blanket that was shown at the - at the 1989 trade	show,	18	•	Do you recall seeing a Gaym Not specifically, no.	et cympit:	
1.0	have any a hour was it instead for years to insert the h	7 i	10		INDESTRUCTIONALLY, DO.		

21 the hose? A. I don't recall.

Q. You designed the blanket didn't you? 23

A. Yes.

Q. And you don't recall how you designed the

19 how was -- how was it intended for users to insert the hose?

20 How was the blanket constructed such that users would insert

A. Not specifically, no.

How about a Cincinnati Subzero exhibit?

A. Not specifically.

Q. Do you recall seeing a Mallinckrodt exhibit?

A. Not specifically, no.

Q. Did you collect literanare from the booths

25 that you visited?

21

23

24

22

_		denseit Depo-Squir
Ran	·	
	Page 5	1 - 48c 3
1	A. I don't recall.	
2	Q. Do you recall actually visiting any booths or	The state of the s
	do you recall just walking around the show?	
4	A. I think I visited with some booths.	4 MS. SORANNO: Objection, calls for 5 speculation.
5	Q. Do you recall which ones you visited?	1
6	A. I do not.	6 A. I couldn't say for certain. 7 BY MR. KURZ:
7	Q. Do you recall seeing anyone from Mallinckrodt	,
1	at the show?	Q. Does Augustine usually take orders for     products at its trade shows?
9	A. I do sot	10 MS. SORANNO: Objection, lack of
10	Q. Do you recall seeing any other products other	11 foundation.
111	than Augustine at the show? Can you recall any other product	12 A. I couldn't say for certain.
	that you saw at the show aside from Augustine's?	13 BY MR. KURZ:
13	A. Not specifically, no.	14 Q. Do you ever recall Augustine taking any orders
14	Q. Take a moment and look through the brochure	15 for products at its trade shows?
	marked as Exhibit 4 and then tell me whether you see any	16 A. I think we generate lead cards for for
	reference to any model numbers in there?	17 hospitals.
17	A. I don's no.	18 Q. Do you ever recall anyone at Augustine ever
18	Q. Do you recall when Augustine decided upon a	19 taking any orders for products at trade shows?
19	model number for its lower body O.R. blanker?	20 A. Not that I recall, no.
20	A. I do not.	21 Q. Do you recall distributing any lead cards at
21	Q. Do you know whether the lower body O.R.	22 the 1989 trade show?
	blanket had a model number at the time of the show, the '89	
23	show?	23 A. Not specifically, no. 24 Q. Do you know if any lead cards were distributed
24	A. Not for certain I don't.	25 at the 1989 trade show?
25	Q. How about the upper body blanket, do you know	D
	Page	301
	whether the upper body blanket shown at the 1989 trade shown	1 A. I couldn't say for certain.
2	was referred to by a model number?	2 Q. Do you know how many people visited the 3 Augustine booth at the 1989 trade show?
3	A. I don't recall.	
4	Q. Do you recall what the model number was of the	4 A. I do not.
5	first upper body blanket that was sold to customers was?	5 Q. You don't have any recollection at all?
6	A. I don't recall.	6 A. I remember we were busy. 7 Q. Do you remember whether it was more than
7	Q. Do you know what the model number was of the	
8	upper body blanket that had a single hose connection openi	ing 8 50 people?
9	was?	9 A. I'm certain.
10	A. I don't recall.	10 Q. You're certain it was more than 50?
11	Q. The photograph in the - in the middle of the	11 A. Yes. 12 Q. Are you certain it was more than a hundred?
12	brochure of Exhibit 4, the - the hose card that does not	1
13	have a hose in it, does that picture show any means to	13 A. Yes.
14	facilitate the customer inserting the hose in to the plastic?	14 Q. Are you certain it was more than 200?
15	A. It's not obvious from looking at the picture	15 A. Yes, I'm pretty sure. 16 Q. Over the course of how many days did you com
16	here, no.	Q. Over the course of how many days and you com
17	Q. Do you see anything in the picture that	17 to an understanding that there were over 200 people who
18	would would show that?	18 visited the Augustine booth at the '89 trade show?
19	A. No, I don't.	19 A. Over the couple, two or three days, I think,
20	Q. Do you see anything in any of these three	20 that I was at the booth.
21	photographs of Exhibit 1, 2, 3 that would show that?	21 Q. And you personally saw over 200 people come
22	A. I do not.	22 through the Augustine booth?
23	Q. Do you know if someone at Augustine was in	21 A I couldn't say for certain, no.
123	charge of taking orders from customers at the show, the '8	39 24 Q. How do you know that there were over 200
124	trade show?	25 people that visited the Augustine booth?

Q. Did there come a time that Augustine decided 18 to change the design of the upper body blanket that's shown 19 in Exhibit 1 and Exhibit 4 to provide only a single entry 20 port?

21 A. Yes.

Q. Do you recall approximately when that was? 22

21 A. I don't recall.

Q. Were you involved in the design of the upper 25 body blanket that incorporated that change?

Page 61 - Page 64

17 Q. So you understand that there was feedback from 18 clinicians that they were only using one port? 19

A. Yes.

20 Q. Is that one port of the two ports that were 21 available on upper body blankets?

A. I believe so. 23

Q. But you don't have an understanding as to

24 whether clinicians ever used Augustine's upper body blanket 25 that had two ports, is that right?

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10

20

21

22

23

24

25

A.

Q.

25 Augustine decided to go with a single opening upper body Kirby A. Kennedy & Associates (612)922-1955

18 the hose card was applied or before the hose card was

A. I believe it was done afterwards.

MS. SORANNO: Objection, lack of

Q. Any other reasons that you were aware of why

19 applied?

21 foundation.

23 BY MR. KURZ:

20

Page 65 - Page

A. I was for one, I don't recall others.

Could it have been you?

Q. Who was primarily responsible for that?

Any other changes you recall, aside from

Q. Was Tom Anderson?

A. Could have been.

I don't recall.

Could have been.

_	po-Squish Conde	D 50	Randy Arno
	Page 69		Page 7
	designing a new hose card, that were made from going from	1	then folded along the score line and mated the B half with
2	a upper body single port blanket to an upper body dual port	2	the A half. And the B half had a plug that was scored which
3	blanket?	3	was removable.
4	A. You mean to facilitate that change?	1	Q. When you say "a plug that was scored" are you
5	Q. Yes.	5	referring to this dotted line circle shown
6	A. No.	6	A. The score line, yes.
7	Q. This is a drawing that was made by	7	Q in B? And you say you don't recall whether
8	Mr. Anderson yesterday, I'll show you it's Anderson	8	the the blanket within the hole of circle A was cut prior
9	Exhibit 3.	9	to it being sent to customers?
0	A. Okay.	10	A. I don't recall.
ì	<li>Q. Does this comport with your understanding of</li>	11	Q. And do you recall - rather strike that. Tom
2	how the hose card was the finalized version of the hose	12	Anderson testified yesterday that once this was affixed to
3	card that was used in connection with the dual port upper	13	the blanket and sold to the customer the customer would
•	body blanket?	14	either push the cardboard in to the blanket or tear the
5	A. In the second release, yes.	15	cardboard away from the blanket, is that
5	Q. What was the first release?	16	MS. SORANNO: Objection, mischaracterizes
7	<ol> <li>It was our traditional card here.</li> </ol>	17	his testimony.
3	Q. When you say the second release you mean the	18	BY MR. KURZ:
,	release in 1983, in 1993, approximately 1993?	19	Q. Is that your understanding as well?
)	A. Yas.	20	MS. SORANNO: Lack of foundation.
l	Q. And you're distinguishing that from the hose	21	A. I couldn't say for certain.
!	card that was used as shown in the photograph of Exhibit 1,	22	BY MR. KURZ:
ì	for example?	23	<ul> <li>Q. Do you disagree with his characterization as</li> </ul>
ı	A. I believe so, yes.		I've told you?
5	Q. Can you explain in your own words the	25	A. I don't recall what the instructions on the
	Page 70		Page :
	construction of the hose card that's shown in Exhibit 3?		card instructed the clinicism to use. I think there was
!	<ul> <li>A. Again, it was just a paper-like cardboard</li> </ul>	2	•
}	structure with a adhesive backer on two sides, I believe.	)	Q. Do you have any knowledge of how - how users
1	Q. Which two sides?	4	actually used the entry nozzle way?
3	A. I believe both faces of the A, the front side	5	A. I do not.
,	and the back side had adhesive on them.	6	Q. Do you know why Augustine decided to go from
1	VIDEO TECHNICIAN: Excuse me, I'm going to	7	single port upper body blanket to a dual port upper body
	interrupt you here to change the video. Going off the video	8	blanket?
,	record.	9	<ul> <li>I believe we were getting requests from our</li> </ul>
)	(Whereupon, a brief off the record	10	customers.
	discussion was held.)	11	Q. Did you ever see any of those requests?
	VIDEO TECHNICIAN: Continuing with video	12	• • •
ļ	record, Tape Number 2.	13	Q. Did you ever talk to any customers about those
ı	BY MR. KURZ:		requests?
,	Q. Continuing with your explanation, was the —	15	A. I don't believe so.
i	in looking at the A portion of Exhibit 3 was there a cut-out	16	
•	portion here where there was no cardboard in this circle of	17	• •
	A?	18	
)	A. I believe so.	19	
,	Q. And continue with your explanation as to how	20	add a second port to the upper body blanket, you were aw
	the card was - what the characteristics of the card were.	21	
?	A. I believe the you peeled the liner off the	22	
1	back side of the A portion and adhered it to the blanket, and	23	A. No, I'm not for certain.
	I don't remember whether they pierced the plastic or not.	24	Q. You're not for certain?
•		1	· ·
	And then removed the liner from the front of the A side and	25	A. No.  Kirby A. Kennedy & Associates (612)922-19

Randy Arnold Con-	ienseIt <sup></sup>	
Page 7		Depo-Squis
Q. Do you think you were aware?	A. Idon's recall.	Page 7
2 A. Probably.	Tan Tabil Table.	
Q. And what were you indicated that the reason	4. Do you toward propariting any p	rotorypes with
4 for going to the dual port upper body blanket was feedback	3 the design of two ports that were akin to 4 blanket shown in Exhibit 1?	the design of the
5 from clinicians, is that right?	5 A. I don't recall.	
6 A. I was responding to what the marketing	· · · · · · · · · · · · · · · · · · ·	
7 department was telling me.	4, 20 /or (mile mi) eneastions	
8 Q. And what who what did the marketing	7 possibility of using a dual port design th 8 the 1989 design?	at was the same as-
9 department tell you?	9 A. I don't recall.	
10 A. We had a request to engineer an upper body two	10 Q. Do you recall why it was that	t tomo incondidado.
1) port blanket.	11 use the same design that you used in 198	
2 Q. Did they mention to you that Mallinckrodt had	12 A. I just don't recall.	) <b>)</b> ;
3 a two port upper body blanket?	13 Q. Do you recall whether you -	محالم بالمد
4 A. I don't recall.	14 Were there any drawings that you're aw	
15 Q. Do you recall who you spoke with at at	15 port design, design drawings?	are or or one 1989 dust
6 marketing?	16 A. I couldn't be for certain.	•
7 A. I don't.	17 Q. Did you look at any when yo	Ul Marie affarracione
8 Q. Who would be the person who would normally	18 to redesign the product in 1993 - strike	, .
9 communicate marketing's design changes to you?	19 at any such drawings when you were at	•
O A. It could be anybody from marketing. We've had	20 upper body blanket to go from a single	
a lot of turnover in marketing over the years.	21 port design?	bour occurrent to a crimit
2 Q. Do you recall who would have been the person	22 A. I don't recall.	
to indicate design changes in the early 1993 strike that,	23 Q. Why was there a need to rede	reion the bose sand
4 in the 1993 time frame?	24 to use in connection with a dual port up	-
5 A. I do not.	25 A. I think at the same time we w	
	<del></del>	
Page 7		Page 7
<ol> <li>Q. Do you recall having any discussions with</li> </ol>	1 that change we were lowering the	
2 Scott Augustine regarding changing from a single port upper	2 and there was less plastic in the upp	•
3 body blanket to a dual port upper body blanket?	3 the vertical dimension on these hose	
4 A. Not specifically, no.	4 extreme, so we went to a design that	t had a lower profile to
5 Q. How about generally?	5 it.	_
6 A. It could have happened, I don't know.	6 Q. Was the any other reaso	
<ol> <li>Q. Do you recall discussing those types of</li> </ol>	7 A. It could have been that we	
8 changes with anyone other than the marketing department?	8 gain some more surface area, too, fo	r - for labeling, but I
9 A. I probably discussed it with engineering or	9 couldn't say for sure.	
0 production to see what the ramifications would have been.	10 Q. Were you also looking to	-
<ol> <li>Q. What did they indicate the ramifications would</li> </ol>	11 would facilitate the user's choice of	opening one opening or
2 be?	12 the other?	
3 A. I don't recall.	13 A. I believe so, yes.	
4 Q. Do you recall whether there was a change in	14 Q. Isn't that one of the reason	ns why you wanted
5 the way the surgeons - strike that. Do you recall whether	15 to redesign the hose card?	
6 there was a change in the way operating rooms were set up	16 A. That was one thing we we	ere looking for when we
7 that facilitated the need for a hose opening on either side	17 were redesigning, yes.	<del>-</del>
8 of the upper body blanker?	18 Q. When you were redesigning	ng the hose card did
	19 you consider having a card that did	not have a cardboard
9 Mrs. SORANNO: Objection, lack of		f having a circular
0 foundation.	20 perforated circular center in favor o	n sarring a circum
1 A., No, not that I recall.	21 opening where a hose could be inse	tren musern in months

22 scaled plastic?

A. I don't recall.

Q. You don't recall whether you considered that

25 when you were redesigning the single port to the dual port?

22 BY MBL KUTKZ: 23 Q. WI

23 and fits in the hole

A. Sure.

Q. Could you draw it for me?

Q. Were the hose widths decreased to lower the

25 loft in connection with blankets other than the upper body

A. Not that I recall.

			•	S-2
1	ndy Arnold Conde	a se	It <sup>™</sup>	Depo-Sq
	Page 81			Page
1	arms out blanker?	2		Do you have notes and drawings of your design
2	A. I believe so.	3		card in Exhibit 5?
3	Q. Was the bose card ever redesigned - strike	,		do not.
4	that. You mentioned that one of the considerations in	5		Oid anyone is it your normal practice in
5	redesigning the bose card in the upper body blanket to that			ar and a half to make notes and drawings of de
	as shown in Exhibit 3 was to accommodate the smaller diameter	7	-	at you make?  When it's a product that I'm a primary
7	rubes?	'	engineer of	•
8	A. Yes.	9	•	m, yes.  Who's the primary engineer of the bose card of
9	Q. Was any such change made in the hose cards for		Arnold Ex	
ı	the other blankets to accommodate smaller diameter tubes?  A. It wasn't necessary by virtue of the fact that	11		Tom Anderson.
•	, , , , , , , , , , , , , , , , , , , ,	12		When you're not the primary engineer of a
2	the hose was addressing the - the tube at a different angle	13		ou don't take any notes at all?
3	on - on other products.	14		Generally not.
4	Q. Could you go in to some detail about what that	15		Or make any drawings?
	difference was with the hose angle and why it wasn't	16		Generally not.
6 7	necessary?  A. Well, on our other blankets this card is - is	17		Do you know whether Mr. Anderson made any
		1 .	-	rawings of the design of the hose card of
	mounted in line with the length of the tube, and how long it	19	Exhibit 5?	-
9	is is really irrelevant. On the upper body blanket this was	20		l couldn't say for certain.
	mounted transverse to the tube, and the longer it was the more it wanted to go up and around the curvature, and less	21		Have you ever seen any?
1	was better.	22		I don't recall.
		23		Have there been any other nozzle entry design
3	Q. When did Augustine begin selling blankets that	24	-	stine ever incorporated in to a blanket which i
	incorporated the hose card design that you've depicted in Arnold Exhibit 57	25	_	than the designs of Anderson Exhibit 5 and 3
_	Page 82	-		Pa
1	MS. SORANNO: Objection, lack of	1	Amold E	
2	foundation.	2	<b>A.</b>	I believe so, but I couldn't say for certain.
3	A. I don't know.	3	Q.	Do you recall any changes of any other nozzie
4	BY MR. KURZ:	4		
5	Q. Do you know if blankets are currently being	5	٨.	I think we have a
6	sold that have the hose card design in Exhibit 5?	6	Q.	Strike that, I did not complete the question.
7	A. I believe so.	7	Can you o	describe any characteristics of any other hose
B	Q. Do you know approximately when that was begun?	8		I think we have a small rectangular hose card
9	A. I couldn't say for certain.	9	that's use	d with our - our pediatric line of blankets.
, כ	O. Was it within the past year?	10	Q.	Who designed that hose card?
1	MS. SORANNO: Objection, lack of	hi	À	I couldn't say for certain.
	foundation.	12		Were you involved in its design?
3	A. I believe so, but I couldn't say for certain.	13	-	Possibly.
4	BY MR. KURZ:	14	Q.	Do you know approximately when it was
5	. O. Did you work on the redesign of the hose card	15	designed?	
<i>3</i> 6	- strike that. Did you work on the design of the hose card	16	A.	When we introduced the pediatric line of
7	that's depicted in Exhibit 5?	17		
	A. I did.	18	0.	Who else besides yourself would have been
8		19	•	in the design of that card?
9		20	A.	I couldn't say for certain.
0.	A. Tom Anderson.	21	Q.	Does that card have a a open hole in the
i	Q. Anyone else?	1	ų. marthar−	d or a - or is it closed with cardboard or any
2	A. Not that I can say for certain, no.			OR 8 OF IN IT CITATED MINI CONTROL OF THE
3	Q. And you say that for the last year and a half	23		MS. SORANNO: Objection, tack of
4	you've kept a notebook, right?	24	foundation	
	A. Yes.	130		-

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Condenselt™
 Depo-Squish
                                                                                                                       Randy Arnold
                                                            Page 85
                                                                                                                                Page 87
          A. I believe it's open.
                                                                                   And then it says, "Exhibit 1 to the affidavit of
  2 BY MR KURZ
                                                                       2 J. Randall Benham. Augustine Medical maintained a display
          Q. Is the blanker within the open circle of the
                                                                       3 booth during the entire period". Then it sens, "Affidavit of
  4 hose card cut prior to the customer receiving the blanket?
                                                                       4 Dr. Scott D. Augustine". Then it says, "On display at the
                  MS. SORANNO: Objection, lack of
                                                                       5 booth was the Bair Hugger dual port upper body blankes, a
                                                                          product substantially identical to the blanket Mallinckrodt
  6 foundation.
          A. I believe so, but I couldn't say for certain,
                                                                       7 has accused of patent infringement". Do you see that?
                  MS. SORANNO: Counsel, let's go off the
                                                                               A. I see that,
     record and talk about timing here.
                                                                               Q. Do you agree that the product on display at
                 VIDEO TECHNICIAN: Going off video record.
                                                                      10 the booth was substantially identical to the blanket that
 11
              (Whereupon, a brief off the record
                                                                      11 Mallinckrodt has accused of patent infringement?
 12
               discussion was beld.)
                                                                                       MS. SORUNNO: Objection, lack of
 13
              (Whereupon, a lunch recess was taken
                                                                      13 foundation.
 14
               from 12:10 to 1:30.)
                                                                             A. I'm not sure.
 15
                 VIDEO TECHNICIAN: COntinuing with video
                                                                      15 BY MR. KURZ:
 16 record.
                                                                      16
                                                                           Q. You're not sure. Looking at Page 14 it says
 17
                 MR KURZ: During the break we had a
                                                                      17 - right before the conclusion there's a paragraph that says,
 18 discussion about what to do about the exhibits that have been
                                                                       18 "Mallinckrodt claims that Augustine Medical's dual port upper
19 marked in connection with this deposition, which exhibits
                                                                      19 body blanket infringes the 924 and 439 patents". Then it
20 constitute the three original photographs of the - of what
                                                                      20 says, "The same blanket however, was invented known by "
21 purport to be the 1989 trade show, A.S.A. show in New Orleans
                                                                      21 others or on sale more than one year prior to Mallinckrodt's
 22 and the original of the "Normothermia In The O.R." brochure.
                                                                      22 allowed date of infringement". Do you consider - Γm sorry.
23 And Augustine counsel has indicated that she will not
                                                                      23 I read that wrong, "and on sale more than one year prior to
24 relinquish those originals to become to our possession or to
                                                                      24 Mallinckrodt's alleged date of invention". I think I said
25 the possession of the court reporter to - to go along with
                                                                      25 "infringement", sorry. Do you have an opinion as to whether
                                                            Page 86
 I the original deposition. So what we have done is we have
                                                                       1 the -- the blanket that was on sale -- strike that, the
 2 color photocopies of those exhibits, which we will mark with
                                                                       2 blanket that was shown at the 1989 trade show is the same
 3 numbers that correspond to the originals but maybe we'll put
                                                                       3 blanket as, for example, the Augustine 522 blanket? Do you
    an A next to each one so we'll know that they --
                                                                       4. consider them to be the same?
                 MS. SORANNO: That's fine.
                                                                               A. I do, yes.
                 MR KURZ: - correspond to them, with the
                                                                               Q. You do?
                                                                               A. Yes
 7 understanding that we can have reasonable access to the
    originals as reasonably requested.
                                                                               Q. Can you tell me if - are there any
                                                                       9 differences between the two blankets?
                 MS. SORANNO: Yep, that's fine.
10
                 MR KURZ: Okay.
                                                                               A. Manufacturing techniques have changed a lot,
            (Whorespon, ARNOLD Deposition Exhibit
11
                                                                      11 but.
             Numbers 1A - 4A were marked for identification
12
                                                                               Q. Your opinion is the blankets themselves are
13
             by the Court Reporter.)
                                                                      13 substantially identical?
14
                                                                               A. Substantially the same, serve the same
15
        Q. Let me hand you a document that's entitled
                                                                      15 function.
    "Momorandum In Support of Defendant Augustine Medical, Inc.'s
                                                                               Q. Well, serving the same function doesn't mean
17 Motion For Summary Judgment". Have you seen that before?
                                                                      17 they're the same does it? Or does it to you?
         A. I don't recall.
                                                                               A. Well, specifically what are you asking?
                                                                               Q. I'm asking you whether the construction of the
19
         Q. Okay, I'd like to direct your amention to
20 some statements that were made in the - in the memorandum.
                                                                      20 blanket was the same, is that a fair characterization that
21 If you could turn to Page 4, please? In the first paragraph
                                                                          the blanket shown at the 1989 trade show is the same as the
22 there's a statement there that says, "The 1989 annual meeting
                                                                      22 Augustine 522 blanket?
```

24

23 of the American Society of Anesthesiologists, 1989 A.S.A.

24 mosting, was held in New Orleans from October 14 to

Q. So you disagree with the statement in the

A. No, there's differences.

MS. SORANNO: Is it plugged in? MR KURZ: YOL 10 MS. SORANNO: There we go. 11 12 BY MR. KURZ: Q. Starting with the - this plastic cover that 14 is in my hand here did the blanket that was shown at the 1989 14 15 trade show have a plastic cover like this? 15 A. I believe it did. Q. Was it a cover that was substantially 117 18 identical to this one in appearance? 18 A. Pretty similar. 19 Q. What were the differences? 20 A. It might have been larger or smaller in size, 21 22 I don't recall. I don't believe that we attached them to the

Page 91 Q. Did it have a cut-out portion at the head end Q. And did it have -- see this little bit of extra material here coming out of the head portion? Q. Did it have a border of extra material like 9 this is on this blanket? A. Yes. Q. And did it have excess material closing off at 12 the ends of the tubes over here? And I'm pointing to the 13 side of the head cut-out portion. A. Yes. Q. Did it have approximately the same amount of material as is shown here? A. I don't recall. Q. But it had excess material like this? A. Yes. Q. Approximately the same? I don't recall. Q. And did it have - and this is uninflated 22 23 material, is that right?

And that uninflated material on the sides of

A. Yes.

0.

24

25

Q. It wouldn't have been glued to the blanket

10

11

13

116

20

21

23 blanket at that time.

25 like this one, is that --

Ē	11.	- COBC	_	Randy Arnold
1		Page 9.	3	Page 05
L		d cut-out portion you say were present in the in	1	A. Well, this would be the closest to the hody
		nket at the '89 trade show?	2	most tube. There was a
1		I believe so.	1)	Q. I'm sorry.
1	4 Q.		4	The state was a position.
1	5 materia	extending from the head end as I'm pointing to now		
1		ight and left sides of the cut-out?	6	Was there an uninflated portion extending between the lower
1			7	most tubes?
ľ	8 Q.	And going towards the what would you refer	8	
ارا	y to use of	pposite of the head end, would you call it the body	9	4. 1-10 a — heaven'd cont longer will I I
ľ		he foot end? What do you refer to that as?	10	the same of the same is the same in the same in the same is
li:		Foot end.	111	did that uninflated portion meet the ends of tubes like
1	•	Foot end. On the foot end of the blanket did	12	and the state of t
ľ		minifiated material as is shown on this blanket	13	
۱,		fore you right now?	14	A. Yes, it did, yes.
16		Somewhat similar, I believe.	15	Q. And did the uninflated portion on the - on
17	•	Somewhat similar? Yea.	16	
18			17	A. Yas.
19	•	,	18	Q. Can you think of any differences between the
20		I don't know if it was this wide necessarily, d material	19	blanket that's in front of you now and the blanket that was
21	-		20	at the '89 show that you can describe for me right now?
	Q.	It had material?	21	A. The tubes were the upper layer the tubes
22	Α.	Yes.	22	had much more fabric in them, they were larger tubes. The
23	Q.	An uninflated section?	23	77
24	٨.	Yes.		instead of this non-woven. The upper -
25	Q.	Did it have a a cut-out? Do you see this	25	Q. When you say the lowest layer was tissue paper
		Page 94		Page 96
		ed cut-out for the torso?	1	and laminate and what is this?
2	. A.	It had a cut-out. It wasn't an arc at that	2	A. This is a non-woven synthetic.
	time.	_	3	Q. Okay. Anything else?
4	Q.	There was a cut-out though for the torso?	4	A. The upper portion was formed with polyethylene
5	٨.	Ya.	5	and I believe this is polypropylene on this particular cover,
6	Q.	And did it have any means for affixing the		it's got the - kind of a cloudy, milky look to it as opposed
7	the blank	et at the torso end to the patient?	7	to the clear polyethylene sheet that we use for the head
8	A.	There was tape.	8	drape. The hose cards are of our subsequent design.
9	Q.	There was tape. Was the tape affixed to the	9.	
0	blanket a	s this is here and then peeled off?	10	that you're looking at now were of a subsequent design?
i	٨.	Yes.	11	A. Yes. And there might be less tubes than what
2	Q.	Similar to this design right here? Again, it	12	the initial design was, I believe.
3	was not -	you say it was not in an arc shape?	13	Q. Anything else?
4	A.	It was not in an arc shape, no.	14	A. Well, the shape of the cut-out here originally
5	Q.	But it had tape that was affixed to the bottom	15	was, I think, more angular than a nice arc. I think the
6	of the bla	nket that you would then peel off and affix to the	16	space at the head might have been a little bit narrower, but
7	patient?		17	I couldn't be for certain.
8	A.	Yes.	18	Q. Anything else?
9	Q.	And did it have	19	A. I think that's primarily it.
0	۸.	No sense warming up the room anymore.	20	Q. Okay.
ı		MS. SORANNO: Okay.	21	MR. KURZ: Why don't we go off the record
2	BY MR. KL	•	1	for a minute.
3		Did it have an uninflated portion extending	23	VIDEO TECHNICIAN: Going off video record.
	-		24	-
5	closer to t	he body most tube?	25	(Whereupon, a brief off the record discussion was held.)
_	93 - Pa		دد	Kirby A. Kennedy & Associates (612)922-1955
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Page 93 - Page 96

Kirby A. Kennedy & Associates (612)922-1955

1	Page 97	T	Depo-Squi
1		í	BY MR. KURZ.
	record.	2	
1	BY MR. KURZ:	,	4. And you indicated that there was uninflated
14		1	material, which i in showing now on the camera at the fore
5	6. Ombit long to make saile may we se for any	5	end before we reach the indentation for the body that was
6		1	also present on the 19 the blanket shown at the 1989 trade show, is that correct?
1,	•	, ,	
8		1 6	MS. SORANNO: Same objection.  A. Yes.
9		9	A, Yes BY MR. KURZ:
1	that we were - some of the material we were talking about	liò	Q. And there's that's at both ends of the
	was over here, can you see that? This is material that	111	Q. And there s = that's at both ends of the indented portion, is that correct?
12			A. Yes.
13		13	A. 1 es.     Q. And you indicated that the blanket at the 1989
14		14	
15	MS. SORANNO: Objection, asked and	15	trace show had a cut-out for to accommodate the body, be that it wasn't curved like this, is that correct?
16	answered.	16	A. Yes.
17	BY MR. KURZ:	17	A. Yes.  Q. And you indicated that there was uninflated
18	Q. Correct?	18	
19	A. Yes.	19	like this, in the blanket that was shown in the 1989 trade
20	Q. And holding up again the additional uninflated	20	
21	material closing off the tubes at the head end that we	21	MS. SORANNO: Same objection.
22	discussed, this material over here, and you indicated that	22	A. Yes.
23	the blanket at the 1989 trade show had such material, is that	23	·
24	correct?	24	Q. And that there was uninflated material
25	MS. SORANNO: Objection, asked and	1	extending across this space, is that correct, in the blanket
	Page 98	-	
,	rage ya	١,	Page 10 at the 1989 trade show?
,	A. Yes.	1 2	MS. SORANNO: Same objection.
3	A. 1G. BY MR. KURZ:	3	MS. SORANNO: Same objection.  A. Yes.
4	Q. And the material, additional uninflated	4	A. 1 GS. BY MR. KURZ:
5	material at the head end, aside from the cut-out portion was	5	Q. And you also indicated that there was tape
6	this material both to the left and right of the cut-out	4	Q. And you also indicated that there was tape affixed to the underside of the blanket at the 1989 trade
7	you indicated that the blanket at the 1989 trade show had	7	show that had a peel-off portion which would then be adhe-
8	minflated material extending such as this, is that correct?	8	to the torso of the body, is that correct?
9	MS. SORANNO: Objection, asked and	9	MS. SORANNO: Same objection.
10	answered.	10	A. Yes.
11	A. Yes.	11	MR. KURZ: Why don't we go off the record.
12	BY MR. KURZ:	12	VIDEO TECHNICIAN: Going off video record.
13	Q. And then material you indicated that there	13	(Whereupon, a brief off the record
14	was material extending beyond the ends of the tubes on both	14	discussion was held.)
15	the left and right sides of the blanket, this is one such	15	VIDEO TECHNICIAN: Continuing with video
16	side, here is the other, and you indicated that the blanket	16	
17	at the 1989 trade show had such material, is that correct?	17	MR KURZ: Why don't we mark we'll mark
18	MS. SORANNO: Same objection.	18	this blanket that we just looked at as the next Arnold
19	A. Yes.	19	exhibit, which would be Exhibit 6. We can mark that in a
	BY MR. KURZ:	20	moment.
21		1	BY MR. KURZ:
	-	22	Q. Okay. Okay, do you recognize this blanket
			that I've just placed in front of you as a model Bair
23 24	•	24	Hugger model 525 lower body blanket?
24 25		25	A. I refer to it as a lower body cover.
_		۲,3	Page 97 - Page 1
د: ۱	No. 8. Warmady & Associates (612)022-1055		Dage 117 UARA 1

Page 103 27
I A. Yes.
2 Q. And was there uninflated was there an
3 uninflated section extending from the ends of the tubes
4 towards the patient's head on the blanket shown at the 1989
5 trade show?
6 A. Yes.
7 Q. Was there a do you consider this to be an
8 uninflated viewing area?
9 MS. SORANNO: Objection, lack of
10 foundation.
11 BY MR. KURZ
12 Q. What's the purpose of this material do you
13 know?
14 A. It's to facilitate patient viewing and - and
15 provide areas for placing surgical instruments.
16 Q. Was that the purpose of the uninflated area on
17 the blanket shown at the 1989 trade show?
18 A. I believe so.
19 Q. Was there an uninflated area with - that
20 extended inward from the head most end of the blanket, as
21 that which I'm showing here with my hand and showing the
22 camera, at the blanket on the blanket at the 1989 trade
23 sbow?
24 A. I coulon't be for certain on time.
25 Q. You don't remember?
02 Page 104
1 A. I don't recall.
2 Q. Was there my means for this is the head
3 end, right?
4 A. Yes.
5 Q. Was there any means for affixing the
6 uninflated edge here to the patient on the blanket at the
7 1989 trade show?
8 A. Yes, it had tape on it.
9 Q. Was the tape affixed to it such as this is and
10 then it would be peeled off and adhered to the patient?
II A. Yes.
12 Q. Just as this is here?
13 A. Similar, I think, I couldn't be for certain.
14 Q. But it did have tape where you would peel off
15 the tape and then affix it - the tape was it affixed to the
16 head end of the blanket?
17 A. Yes.
18 Q. And then you would peel off the backing of the
19 tape and then affix the tape to the patient, is that correct?
20 A. Yes.
21 Q. Did the blanket at the 1989 trade show have
22 any uninflated portion extending towards the foot end of the
21 hlanket?
24 A. Yes, but it was not as substantial as what
25 this portion is here.
Kirby A. Kennedy & Associates (612)922-195.
' <u>-</u>

		Conden	selt	~		Depo-Square
Ran	dy Amold	Page 105				Page 167
		-	1	A.	Just the - the short margin of	material that
1	Q. It was a smaller	portion?		s simil	ar to like the the bead end. I	
2	A. Yes.	į.	3	Q.	Did that cover the feet?	
	Q. And it extended	all the way across the bottom	, 4	Q,	I don't believe so.	
1	of the blanker?		5	O.	Okay, why don't we turn it o	off. Ob. I'm
5	A Yes.	j	3	L.	fore we do that, why don't we	plug it in again.
6	Q. Would you con	sider that to have been a foot	6 50	ту. ос	e more - I want to ask you w	bether you - go shead
,	drape?		7 S	orry, or	it on. I just want to ask you	whether you can'
8	A. No. it didn't be	ve a foot drape on it at that	8 2	ng turn	y other differences between the	blanket that's in.
,	time.	·	9 1	20 1 E ALI	you now and the lower body t	planket that was shown =
اردا	Q. It did not bave	a foot drape on it. Did			trade show?	
١,,	in for the second, this bla	anket has a series of openings on		be 1989	The materials have changed	l again. I believe
12	the horsem from which the	e air exits. Did the blanker at the	12	<b>^.</b> .	is a non-woven and the one a	t the trade show was a
113	trade show have a series of	of openings on the bottom from which	13 0	pat tons	ith tissue - or tissue paper wi	th plastic laminate.
114	the air exited such as this	bere?				ottom layer, right?
15	A Yest.		15	Q.	s	unner laver was a
16	O And I assume	the same thing is true with	16		ylene plastic as opposed to thi	s polypropykas.
117	Evhibit 6 as far as boles	on the bottom from which air	1	polyeth	yiene puistic as opposed a	• F/1
18			18		Anything else? The addition of the foot dr	ane And I
119			19		t be for certain, but I think th	err might have been an
20	Q. Did the blank	ets at the '89 trade show	20	coulda	I be for certain, but I unite a	dom
21			1		nal two tubes on the outside of	<del></del>
22			22	Q		one ones. And then
22		you think it means?	23	^	I think those are use primi	hour the - the
- 1			1	the po	ssibility of - I'm not certain a ion of the - the viewing area	down into the blanket at
24	·		25	टराज्या	ion of the - the viewing area	Page 10
1	9. 12)	Page 10	6			t age 10
1		_	1	the to	p end.	
	A. Yes.	understanding of the term	2	(	Q. That's this over here?	
-	-	monstanding of the term	3		A. Yes.	
- {	3 self-erect?		4		Q. Anything else? Did the	ne blanket at the 1989
- {	4 A. Yes.	and the form an arch when	5	trade	show have a continuous or	earn all across this end over
l	5 Q. Did they be	ive a tendency to form an arch when	6	_		
l	6 they were inflated?	to all own the distinction the	1,		A. I believe so.	
- [	7 A. When they	were placed over the dummies on the	8		Q. Okary, why don't we	go ahead and turn this off.
	8 O.R. table.		1 -		MR KURZ: Let's bu	ive this marked as
	9 Q. But when I	they weren't placed on dimmies on the	2 10		ibit Number 7, please.	
	10 O.R. table they did t	sot have a a tendency to form an arch	"   "		CIVIL	Deposition Exhibit
1	11 A. I coulden't	be for certain.	1		Numbers 6 and 7 we	re marked for identification
-1	12 Q. Doesthis l	blanket here have a tendency to form	li	-	by the court reporter	.)
- 1	13 an arch?				THE WITNESS: CO	uld I quick get another
- 1	14 A. If you plan	ce a body underneath it.			ik of water?	
- 1	. O Somefeet	H VOIL'RE CONCERNED THE	1	5 W.H.	ME KIRZ: SUR.	why don't we take a
1		of the blanket, the two blankets that	- 1		-minute break.	•
	to the landard of today	is the same as the self-clothing toward	:   <u>'</u>		WE CORANNO I'	l get it for you.
	18 of the blankets that	were shown at the 1989 trade show?	- 11	8	VADEO TECHNICIA	IN: Going off video record.
	10 A. Fairly sim	rilet.		9	(Whereupon, a brief	off the record
	an O What was	the difference, if any?	1	20	وأحط مصد مستسديد	1)
	A Resiculty	the same. There was more material	- 1	21	GIRCUSSION WAS DETO	AN: Continuing with video
	as on the top of the hi	ankets at the '89 show, but the same		22		<b>-</b> ≠ <b>*</b>
				23 rec		•
	23 basically.	there any material at the foot end of	ŀ	24 BY	MR KURZ:	e individuals who helped
	24 Q. And Was	989 trade show for covering the feet?	į	25	Q. Were you one of th	Page 105 - Page
	125 the blanker at the I	707 0				Late 103 - 1 wer

Page 109 - Page 112

Q. Approximately how long ago did Augustine start,

A. No, I can't.

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₹a	ndy Arnold	Condens	elt™	Depo-Squis
	•	Page 113		Page 11
1	Q. Have you ever heard any allego	ations that	Α.	I couldn't say.
2	Mallinckrodt employees improperly gain	ned access to a Polar 2	BY MR.	. KURZ:
3	Bair product?	3	Q.	Why can't you say?
4	A. Yes, I did.	1	A.	If the tray just merely slid out it wouldn't
5	Q. Who did you hear that from?	5	seem ti	hat that would be disassembling it, I don't know.
б	A Dr. Vosskuhler, I believe.	6	Q.	Did Dr. Vosskuhler tell you anything else
7	Q. What did he tell you?	7	about t	the Washington University situation?
8	<ol> <li>A. He showed me some polaroid :</li> </ol>	photographs and 8	A.	Not that I recall.
9	said that some employees of Mallinckroo	dt had been caught   9	Q.	Can you think of any articles that were ever
0	disassembling one of our Polar Air units	at some facility 10	written	about the Polar Bair product?
1	somewhere.	11	A.	I don't recall.
2	Q. Did he tell you where it was?	12	Q.	. Have you ever seen any articles written about
3	A. He did, but I don't recall what	he said.	the Pol	lar Bair product?
4	Q. Did he tell you anything else a	bout that . 14	<b>A</b> .	. I couldn't say for certain.
5	situation?	15	Q.	. Did you discuss the statements that were made
6	<ol> <li>Not that I recall.</li> </ol>	16	by Dr.	Vosskuhler with anyone else?
7	Q. Did he tell you what what h	e meant by	A.	. Not that I recall.
8	disassembling?	. 18	· Q.	. Have you ever heard from anyone else aside
9	A. No, I don't think we discussed	lit. 19	from I	Or, Vosskuhler that any allegations that Mallinckr
0	Q. Does the does the Polar Bair	r product have a 20	emplo	yees viewed a Polar Bair product?
1	evaporation tray?	21	A	. Not that I recall specifically, no.
2	A. I believe so.	22	Q	. What else did Dr. Vosskuhler - Dr. Vosskuhler
3	<li>Q. What does the evaporation tray</li>	y do? 23	show y	you aside from photographs?
4	MS. SORANNO: Objection, la	ick of 24	A	. I don't recall anything else.
5	foundation.	25	Q	Did he show you any correspondence?
		Page 114		Page
l	A. There is, as with any air condi	tioning unit,	A	. I don't recall.
2	if the humidity level in the environment	where it's being . 2	Q	. Was anyone else present when you talked to
3	used gets substantial there's a certain an	sount of 3	him?	•
4	condensation which collects in the in	the heat exchanger, 4	A	. I don't recall.
5	and the evaporation tray was just a mean	ns of collecting this	Q	Do you know why he told you about that subject
6	condensation and evaporating it.	6	metter?	?
7	BY MR. KURZ:	7		MS. SORANINO: Objection, calls for
8	Q. Was there any way of - of cha	ocking whether 8	speculi	stion.
9	there was water in the evaporation tray?	9	A	He and I share an office, that could have
)	A. I don't recall.	10	someth	sing to do with it.
i	Q. Do you recall whether the evap	ponation tray	BY MR.	KURZ:
2	slid in and out?	12	Q	Did be tell you whether be thought that the
3	MS. SORANNO: Objection, Is	ick of	Mallin	ckrodt employees did anything wrong?
4	foundation.	14		. I don't recall.
ţ	A. I believe it does.	1:	, Q	). Did you reach an understanding in your own
	BY MR. KURZ:	10	mind a	as to whether you thought Mallinckrodt employees did
	· · · · · · · · · · · · · · · · · · ·			

17 anything wrong?

A. I don't recall.

21 facts in the case, I don't understand.

Q. Do you have an opinion about that now?

Q. Did Dr. Vosskuhler relate to you any

23 discussions he had with any other individuals regarding -

A. What was the question again?

A. I don't understand - I haven't heard all the

24 regarding the Mallinckrodt viewing of the Polar Bair product?

18

19

20

22

25

Q. Would that constitute disassembling the

Q. You believe it does. Would you think that if 18 someone slid out the evaporation tray that they would be

MS. SORANNO: Objection, lack of

19 considered to be disassembling the Polar Bair product?

21 foundation.

22 BY MIL KURZ

24 product to your knowledge?

20

23

**\*** 

De	po-Squish Conde	13 50	It Randy Arnold
Г	Page 117		Page 119
1	Q. Did Dr. Vosskuhler relay to you any	1	A. Well, I worked on it for a little bit, Greg
2	conversations he had with anyone else regarding Mallinckrodt	2	Hamlin might have at some point.
3	employees viewing the Polar Bair product?	)	Q. What does Greg Hamlin do?
4	A. I don't recall.	4	A. He's a engineer with R & D.
5	Q. Did you consider the until the first sale	5	Q. Anyone else you can think of?
6	of the Polar Bair did you consider the exterior of the	6	A. Tom Anderson might have on occasion.
17	product to be a company trade secret?	7	Q. Anyone else?
8	MS. SORANNO: Objection to the extent it	8	A. Dr. Augustine was certainly there as a advisor
9		9	and supervisor of the project.
10	A. I hadn't given it any thought.	10	Q. Do you ever recall any labeling on the Polar
11	BY MR. KURZ:	11	Bair product that indicated that it was confidential?
12	Q. Did you think that it was that the exterior	12	A. I don't recall.
13	of the Polar Bair product was confidential in any way?	13	Q. You don't recall seeing any confidential
14	MS. SORANNO: Same objection.	14	stickers or anything like that?
15	A. I hadn't given it any thought.	15	A. I do not.
16	BY MR. KURZ:	16	Q. Aside from the R & D area that you described
17	Q. Did anyone tell you to keep the Polar Bair	17	was the Polar Bair product ever located even temporarily
18	product confidential?	18	anywhere else within Augustine?
19	<ul> <li>A. I wasn't involved in the product in any sense</li> </ul>	19	MS. SORANNO: Objection, lack of
20	that I would have occasion to.	20	foundation, calls for speculation.
21	Q. But did anyone ever warn you not to talk about	21	A. I don't recall.
22	the Polar Bair product?	22	MR. KURZ: Counsel, why would you say it
23	A. Not that I recall, no.	23	would be speculation for me to ask the witness whether he
24	Q. Have you ever seen any reference to the Polar	24	knew whether the product was located in anyplace other than
25	Bair product being a confidential product?	25	the R & D department?
$\vdash$	Page 118	Γ	Page 120
l,	A. Not that I recall.	1	MS. SORANNO: Because he did not have
2	Q. Within Augustine was access to the Polar Bair	2	involvement with the entire project. He said he was involved
1	product restricted to your knowledge?	3	from time to time. And you have not laid the foundation that
4	A. I guess no more so than any other product that	4	he knew the whereabouts of the Polar Bair throughout the
5	we work on in R & D.	5	entire existence of the project.
6	Q. Where was the product was there a	6	MR. KURZ: Well, knowing the whereabouts
7	particular location where most of the work on the Polar Bair	7	of the product during the entire development process is a
8	product took place?	8	different question than knowing whether he's ever seen it or
9	A. Within the R & D area of Augustine Medical,	9	was aware of it anyplace other than the R & D department.
10	yes	10	And I would ask you to refrain from unnecessary objections.
h	Q. Is that a restricted area?	11	MS. SORANNO: My objection stands. I'm
12	A. Yes.	12	not withdrawing my objection.
113	Q. Are there signs that indicate that it's	13	MR. KURZ: Oksay, and I'm going to ask you
14	restricted?	14	in the future to refrain from that as - I'll just leave it
15	A. It's key code access.	15	at that for the time being.
16	Q. Are there any signs that you're aware of that	16	MS. SORANNO: That's fine.
17	indicate that it's restricted access?	17	MR KURZ: And ask you to refrain from
18	A. I don't believe so.	18	
19	Q. Who worked on the design of the Polar Bair?	19	MS. SORANNO: Your objection is noted.
20	A. The primary engineers on the project were	20	
21		21	Q. I want you to think carefully and think
22	Q. Anyone else work on it to your knowledge?		whether you can recall ever seeing the Polar Bair unit
23	A. Other people had a hand in it from time to	23	
	time, but they were the principals.	24	
25	Q. Can you think of who else had a hand in it?	25	answered.
1	· · · ·	1-	((12)022:1055

Ra	ndy Art	nold Conde	nse	It <sup>54</sup>	Depo-Squi
l		Page 121	1		Page 13
1	A.	I just don't recall.	1	Mallinckrodt shortly after yo	ou started with the company?
2	BY MR. K	URZ:	2	A. I think probably m	y first recollection was
3	Q.	Have you ever seen it anyplace outside of	3	Scott telling me at one point	that Mallinckrodt had taken a
4	Augustin	se?	1	interest in our company and	had come up to the Twin Citie
5	Α.	I've seen it in transport.	5	for a visit.	
6	Q.	When did you first see it in transport?	6	Q. Did that visit occur	r while you were at
7	-	I don't recall specifically.	7	Augustine or prior to that?	2
8	Q.	Where did you see it in transport?	8	A. Prior to it, I believe	e
9	À.		9	Q. What did he tell yo	ou about Mallinckrodt's
10		opment of - of manufacture and R & D effort, and	10	interest in the in the produ	act?
11		e to time the chief engineers had occasion to	111	A. I don't recall.	
12		the machines to other sites.	12	O. Did he did there	come a time when he told
13	Q.	Who are these outside vendors?	1	you that Mallinckrodt no lor	
14	A.	I don't recall specifically.	14	product?	
15	Q.	You don't recall any of them?	15	A. I don't recall.	
16	Q. ٨.		16		ell you about Mallinckrodt?
17	Q.		17	A. I don't recall.	,,
18	-	Put in the back of a van.	18		ons did he talk to you about
19	۸.	_	1	Mallinckrodt's interest in ar	
20	Q.	An Augustine van or an employee van.	20	A. I don't recall.	iy produce or required s.
	A.	• • • • • • • • • • • • • • • • • • • •	21	Q. Was it more than a	· ·
21	Q.	When you recall seeing it transported do you	22	•	, I doa't remember.
22		r who was driving the van?	23	•	y, why don't we take a short
23	A.	I can think of occasions when Hamid		break.	y, why dod t we take a short
24	transport		25		Table Coing off trides mound
25	Q.	Anyone else?	+	VIDEO TECRNIC	TAN: Going off video record.
	•	Page 122	2		Page 1
ł	A.	Not that I recall.	] 1	(Whereupon, a brief	recess was taken
2	Q.	Were you with him when he transported it?	2	•	
3	<b>A</b> .	No.	.3		N: Continuing with video
4	Q.	Did you help him load it on?	4	record.	
5	A.	I don't recall.	5		I just wanted to say that
6	Q.	You just remember seeing it being loaded on to	6		u today. Thank you very much
7	a van?		7	for your time. I also wanted to	ask counsel if in addition
8	A.	Yes.	8	to bringing in the polaroids of	– the originals of the
9	Q.	On how many occasions?	9		
10	A.	Several.	10	could also bring with you tome	orrow, whoever comes to the
11	Q.	And this is during the the development	111	deposition tomorrow brings a s	sample of the blanket with the
12	stage of	the Polar Bair?	12	hose inlet that Mr. Amold drev	w in Exhibit Number 5.
13	Ĭ.	Yes.	13	MS, SORANNO: W	e will bring the upper body
14	Q.	Was there anyone with you when you saw the	14	blanket that you referenced in	Exhibit Number 5, and if we
15	-	ir being loaded on to a van?		have the polaroids, we're chec	
16	- A.	<del>.</del>		produce them.	
17	0.	Have you had any discussions with anyone after	17	•	thank you.
		skuhler talked to you regarding the issue of whether	18	VIDEO TECHNICU	UN: This is the end of the
18		Bair product was or was not confidential?	19		
19		The state of the s	20	- many statement	h, Mr. Arnold, you have the
20	٨		-		represent once it has been
21	Q	When was your first awareness of Mallinckrodt	21	Lafter to LEASEM Aorts (REDOR)(200	mend that was exercise that
22		pany do you recall?	22		mineral mar you control mar
23	<b>A</b> .	I think probably when I initially started at		night.	
24	the comp	oany, shortly thereafter.	24		
25	Q.	Was anything said to you regarding	25	(Whereupon, at 2:48	p.m. on Tuesday,

Depo-Squish	Condenselt <sup>™</sup>	Randy Arnold
7 1	Page 125	Face 127
February 27, 1996, the taking of the	' TATE OF MONNESCOTA 1	
of RANDY ARNOLD was concluded.	3 COUNTY OF HEMITEPON	<b>SS</b> .
3	4	
5 4 5	5 ARNOLD, on the 27th day Corner, Minrascolis, Min	ok the deposition of EANDY of February, 1994, at 1400 IDS INSIGNAL
6	4	
7	7 the Courty of Herespin, 5 virtue thereby I was duly	there a Notary Public in and for Stars of Minnesota, and that by authorized to ediminister up outly
8	That the writings before the security the s	ere manufacing was by and first whose words and containing but the K
9	truth relative to miss cause	K
10	That the testimony of	f mid witness was recorded in transcribed ions typewrong woder sty martine is a true record of the
н	direction; and that the day 12 metassey given by the wi	carrios is a true record of the space to the best of my ability;
12 13	13 That I am not related of the action;	to nor intervened in the eventure
14	14 70	riginal transcript has been
15	15 charged to the purty accidental agreed upon by otherwise agreed upon by 16 made available to all pure	ing the deposition, values Courand, and that copum have been just the same costs, unless Courand;
16 17		signing of the deposition by the reducted by the proceding page;
18	19 That Motics of Filing	
19		AND SEAL this 11th day of March,
20	21 1996.	:
21	, 22	
22	23	
24	24	henifer A. Scharf Court Reporter
14 25	15	
		Day 129
1 (Upon completion, the Original of this Randing and Signing Contricum should be forwarded to the Attorney servicing that	Proper 126	Page 128
2 Deposition.)	2	
) (RANDY ARHOLD) CONFIDENTIAL PORTION	3	•
•	4	
5 I, Randy Arteld, do hereby certify that I have read	5	
the foregoing transcript of any Deposition and believe the	6	
auton to the true and convect (or, except as follows, asting	7	•
the people and line exember of the charge or addition desired.	8	•
and resons why it	9	•
l Page Line Change of Addition Services	10	•
	11	
3	12	
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6 7	16	
7 <b>8</b> .	17	
•	18	
•	19	
1	20	
1	21	
, Sipat	22	
Dund this day of 1996.	23	
(AM)	24	

Page 125 - Page 128

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D 4 3 170 3	V A D X	ioi n				Com	dense	t. ™				100 -		
RAND					<del></del>			11				89 - 8	ttorne	y/client
189 [30]		4:11		77:7		95CV00	514 [1]		110:25			18:12	19:22	20:1
	13:2 16:17	14:24 22:11	1996 (6)	1:18	3:4	1:8	-30		agree (1)			20:14	23:5	
	23:1	23:12		126:23	127:5	a.m [2] 1		3:5	agreed (	2}	127:15	April (t	•	4:2
	29:13	43:21	127:21			A.S.A [7]		32:22	127:16			ATC [4]	94:2	94:13
44:11	45:18	45:21		2:20	86:12			33:12	ahead (6)		79:2	94:14	96:15	
47:18	50:20	50:23		2:20	38:13	- T		86:23			107:7	arc-sha		94:1
51:24	57:22	58:24		58:21	67:14	abdomer		19:18		110:9		arch (3)	106:5	106:10
60:18	93:2	95:20		124:2	124:2			20:15			105:12	106:13		ļ
97:14	98:21	105:20	124:25			abdomin		10:21			109:7 110:15	arca (13)	11:1-	17:15
106:22				61:13		11:13 1 11:19	1:14	11:17	113:10		110:13	17:22	55:6	
'S [1]	86:16			60:14	60:17	ability		19:4	akin			76:8.	103:8 107:25 -	103:16
*The (i)	2:14		60:21 61:25	60:24	61:19		1 27:12	19:4					119:16	118:9
05 [2]	25:9	54:13				1 1 1		10:20	Alan (2)		3:2	areas (1		I
1 [29]	2:20	2:24	20004 (1		2:5	able [7] 8 10:23 1		11:1	allegati	OBS (2)	113:1			1
38:2	38:13	38:15	2400 (2)		127:5		1:19	11.1	115:19			21:19	ra [3]	12:2
39:11	41:5	41:6		1:20		above-er		m	alleged	[2]	87:22			
41:16	45:4	45:5	, , ,	3:4	125:1	3:16		(.)	87:24			12:10	20:25	10:25
45:10 46:19	45:24 47:14	46:11 47:23	27th (2)	1:17	127:5	access (5		86:7	along (s	06.36	20:24 102:19	21:16	20:23	21:2
48:24	51:21	52:8	28(1)	3:5				118:15	71:1 102:21	85:25	102:19	arms (1		10:25
58:21	62:19	63:18	2A (1)	2:20		118:17					86:23	12:1	12:5	12:9
66:2	67:13	69:22	ł	2:18	2:20	accomm	odate i	31	Americ			12:20	13:3	13:10
75:4	85:14	87:J		38:13	38:18			99:14	amount	[2]	92:15	15:11	15:17	16:4
10 (4)	25:9	25:9		69:9	70:1	accused	[2]	87:7			43.11	19:12	80:12	80:21
35:23	85:14			78:6	78:9	87:11		-	ample	•	42:11	81:1		1
108 [2]	2:23	2:23	79:21	80:16	80:20	acquain	m	5:16	Anders		25:19	Amol		1:14
11(2)	54:13	54:13	81:6	83:25		action (1		127:13	27:16 67:13	29:4 68:19	29:7 69:8	2:19	3:13	3:15
Hthm			30 (1)	85:14		add (1)			69:8	71:12	78:6	3:23	38:1	46:11
12 [1]	85:14		3400(1)	2:10				109:4	80:16	80:18	80:20	49:22 80:4	50:2 81:25	79:24 83:10
	86:24	87:16	35 (1)	124:2		added [1]			82:20	83:11	83:17	84:1	86:11	100:18
14 (2)			38(1)	2:20		addition 109:1	[3] 124:7	107:19 126:8	83:25	119:6		108:11	124:12	
J 5 (2)	25:9	54:13	3A (1)	2:20		126:11	24.7	120.6	Anders	OB'8 (1)	25:16	125:2	126:3	126:5
18 (1)	86:25		4 [10]	1:8	2:21	addition	.1	7:11		siologi		127:5		
19 [1]	99:5		2:24	49:23	50.2		28:4	107:21	7:2	21:23		arrive	[1]	18:25
1983 (1)	69:19		57:15	58:12	62:19	1		81:12	4 .	siologi	st's m	arrive	d res	3:23
1989 [13	5)	3:24	66:2	86:21		addressi			6:6	20:4	20:10	22:3	27:14	29:8
4:15	6:1	6:22	439 (1)	87:19		adhere (1		27:22	Apesth	<del>c</del> siolog	istsm	31:22	32:14	
7:20	8:3	8:6	45 (2)	2:9	124:2	adhered		22:25	86:23			arrivit	11) 20	23:8
9:18	12:18	13:14	48(1)	124:25			30:4 100:7	31:4 104:10	angle	11	81:12	article		115:9
14:7 18:20	14:10 19:19	17:5 23:10	49(1)	2:21				20:17	81:15	•		115:12		
23:25	24:10	25:2		2:21	86:12	adhering 21:16	ร (ว) 28:5	20:17	angular	<b>F</b> (1) 1	96:15	articul	latern	34:6
25:15	25:24	26:23	4A (2)					46.0	annual		86:22	aside		14:10
27:15	27:21	28:11	5 (17) 27:17	2:22 29:4	25:19 79:25	adhesive	70:6	26:8	answer	• •	33:23	57:12		68:25
29:11	30:6	32:14	80:4	80:18	81:25	1			33:25	34:1	34:8	98:5		115:23
32:20	32:22	33:7	82:6	82:17	83:2	adminis		127:7	40:14	21.1	34.0	119:16		
33:12	34:3	34:9	83:10	83:19	83:25	advice (	•	111:15	answer	ed on	11:11	assist	[1]	18:12
34:20	39:7	42:16	84:1	124:12		advisab	ility (i)		24:23	31:10	34:12	assum		44:14
44:5 52:25	45:15 53:6	51:12 54:18	50 [10]	35:19	35:24	advisor	[1]	119:8	34:16	37:2	40:3	47:8	65:16	105:16
56:1	56:9	56:12	40:10	40:17	40:18	affidavi	t [2]	87:1	40:7	40:11	40:20	288UM	ingru	44:21
58:1	59:22	59:25	40:24	41:11	60:8	87:3	• •		40:25	44:20	45:1	attach		90:22
60:3	67:8	67:17	60:10	61:15		affix [3]	94:16	104:15	97:16	98:1	98:10	attach		20:22
74:25	75:8	75:11	522 [6]	2:23	88:3	104:19			120:25			1 .		
75:14	85:21	86:22	88:22	89:3	89:20	affixed	מ	71:12	anypla		119:24		ment (	
86:23	88:2	88:21	89:22				94:15	98:22	120:9	120:23	121:3	attem	pt [2]	12:8
90:5	90:14	91:19	525 (3)	2:23	100:24	100:6	104:9	104:15	anytim	e (ii)	61:7	12:19	. •	
97:23	98:7	98:17	101:5			affixing	[2]	94:6	appear	(1)	54:1		pting (2	75:17
99:5	99:13	99:19	55402	11	2:10	104:5			appear	ance (1)	90:18	75:19		
100:1	100:6 102:16	102:2 102:20	555 (1)	2:4		afterwa	rdsın	66:22		ARAN		attend		32:22
102:14	102:16	102:20	6 (5)	2:23	2:25	again (12		11:7	2:1		J (.,	32:24	53:5	53:8
104:7	104:21	105:12	100:19				38:5	49:13	appear	ed m	2:5	53:11		;
	107:11	108:4	7 (4)	2:23	2:25		78:7	94:12	2:10	Ca [1]	2.5	attend	EQ [2]	33:2
1990 (2		67:21	108:10		4.43		102:11	107:6		d res	66:18	53:13	•	06.10
						107:12			applied 66:19	n (1)	00.10	attent		86:19
1991 (3) 65:12	1 00:4	65:8	79 (1)	2:22		ago [13]	8:9	11:15		2011	63:14	Atton		2:14
	. (7.31	(0.10	86 (2)	2:20	2:22	36:10	36:12	36:15	applyi			2:24	2:25	126:1
1993 [7		69:19	9 (2)	1:20	3:5	37:14	37:15	50:8	apprec	iate [1]	77.17	attorn	ey/clie	Dt (I) 24
69:19	73:23	73:24	924 [1]	87:19		50:11	50:17	77:15	approp	riate (4	3:23	110:8		1

69:19 73:23 73:24 924 (1) 87:19 50:11 50:17 77:15 appropriate (4) 5 KIRBY A. KENNEDY & ASSOCIATES (612)922-1955

index Pag

RANDY ARN		<b>U</b>		Cor	ndense	:It™	·			attorney	/S - CE	refulls	
		Based (1)	34:7	71:8	71:13	71:14	bodics (2	1	12:5	100:13	08:20	124:1	1
		basic (11)	5:5	71:15	72:7	72:8	12:20	-	1	DisRati	,	1:18	
110:3 110:8	l	5:8 10:21	13:1			73:4 74:3	body (135			bring [2]		124:13	1
Augustine [104]		15:16 18:5 18:25 23:25	18:6			74:24			13:11 1.	bringing		124:8	1
3:11 3:24	4:4	18:25 23:25 25:22	25:17	75:4	75:20	77:10		15:17	18:4	brings (1		124:11	1
	5:20 7:20	basis [2] 42:14	46:15			79:8	18:9	18:13	19:1	prochar		2:21	}
	10:12	became (1)	62:14		79:15 81:1	80:21 81:5			21:5 23:6		48:20 50:5	49:21 50:8	1
10:14 11:3	11:18	become [2]	10:8		83:24	85:3		22:17 23:21	23:6 23:24		50:3 50:13	50:8	1
	14:11 15:19	85:24		85:4	87:5	87:6	25:15	32:15	32:17	50:20	50:23	50:25	1
	15:19	began (5)	44:2		87:19 88:2	87:20 88:3		33:12	33:13 34:15		51:9 51:19	51:15 51:20	1
20:3 22:3	22:3	53:16 67:7	72:19	88:3	88:20	88:31		34:10 39:15	34:13		58:12	85:22	1
25:18 26:24	27:4	hegin ()	81:23	88:22	89:1	89:3	40:16	41:3	41:6	build (2)		14:18	-
27:7 27:10 29:9 32:10	28:11 40:1	begin (I)	3:1	89:4	89:5	89:17 90:2		42:16	44:10	building		16:1	
43:22 43:22	44:3	beginning (1)	82:8	89:19 90:4	89:20 90:4	90:2	44:18 45:21	44:24 45:23	43:18 I	built (1)	-		1
49:2 49:5	51:8	behalf or	2:5	90:23	90:24	91:4	46:10	46:19	47:2	bunch (2		21:5	1
53:9 53:21 57:11 57:18	56:2 58:23	2:11 3:10		91:5	91:19	92:9	47:3	47:6	47:10	21:12			1
57:11 57:18 59:8 59:14	59:18	belonged[1]	22:14	93:2 94:7	93:12 94:10	93:13 94:16	47:17	48:7 40:1	48:15 49:6	busy (1)			
60:3 60:18	60:22	Benham [1]	87:2	95:19	95:19	96:9	48:23 52:13	49:3 54:2	49:6 54:18	calls [7]		59:4	1
60:25 61:19	62:3	best [1] 6:8	64:1	97:6	97:14	97:23	55:13	56:11	57:19	111:2	112:1 119:20	116:7	ı
62:7 62:8 62:17	62:11 63:3	127:12		98:7	98:15	98:16	57:21	57:25	58:1	Camera		97:9	1
62:14 62:17 64:2 64:9	64:14	better (1)	81:22	98:21	98:23 99:18	99:5 99:19	58:5 62:18	58:8 62:25	61:11 63:7	99:3		102:23	· [
65:7 65:16	65:24	between [9]	47:1	99:13	100:6	100:18	63:18	63:20	63:23	103:22			1
66:5 66:13	66:25	48:23 88:9 95:6 95:18	90:4 102:9	100:22	100:24	101:6	64:3	64:9	64:21	capacit		14:2	1
67;7 67:16 72:16 74:2	72:6 78:3	102:12 107:9	.02.7		101:25 102:13		64:24	65:7	65:24 67:7	card (m)		6:25	ı
78:5 80:21	81:23	beyond (3)	35:25	102:5			66:7	66:25 67:24	67:7 68:13	7:3 26:18	24:13 27:7	26:15 27:22	- [
83:24 85:23	86:16	43:23 98:14		103:4	103:17	103:20	69:2	69:2	69:14	28:15	29:8	29:14	Ī
87:2 87:4	87:18 89:3	bind (11 109:19		103:22	103:22		72:7	72:7	72:20	29:14	29:20	30:7	-1
88:3 88:22 89:20 101:11	89:3 101:19	bit [5] 40:14	89:8		104:21 105:11	104:23 105:12	72:21	73:4 74:3	73:10 74:3	30:20	31:4	31:15	1
109:15 110:25	118:2	92:5 96:16	119:1	105:4	105:11		73:13 74:18	74:3 74:24	74:3 75:20	32:2 53:3	52:24 54:1	53:2 54:5	- {
118:9 119:8	119:18	blanket (224)	2:23	107:9	107:10	107:25	75:24	77:18	78:10	54:6	55:3	55:5	- 1
121:4 121:19	121:20	2:23 6:18 10:24 12:8	6:21 12:19	108:4	109:2	109:5	80:3	80:9	80:12	55:6	55:15	56:5	-
Augustine's [4]	157-12	12:23 12:25	13:1	1	124:14		80:13	80:21	80:25 87:5	58:12	63:14	63:22	ļ
Augustine 8 (4)	123:19	13:11 13:14	14:3	blanke 4:15	ts (17) 4:19	4:13 6:11	81:5 87:19	81:19 89:5	87:5 89:20	64:3	65:25 66:6	66:1 66:18	
Austria [2]	112:19	14:5 14:21	14:24	4:15 13:6	4:19 14:15	0:11 14:16	93:9	94:25	95:1	66:4	68:15	68:17	- 1
112:21		15:9 15:10 15:23 16:13	15:17 18:4	16:10	17:6	19:3	99:4	99:14	100:8	69:1	69:12	69:13	Į
authorized (1)	127:7	18:7 18:9	18:13	19:4	19:4	22:1	100:24	100:25		69:17	69:22	70:1	1
available [4]	34:2	19:13 19:18	20:8	22:4 22:12	22:5 23:21	22:8 23:24	102:5	102:13 106:14		70:21 72:2	70:21 75:23	72:1 76:15	1
34:8 64:21	127:16	20:16 20:17	20:22	22:12	23:21	24:12	102:19	124:13		76:18	76:19	78:3	١
aware [9]	10:8	20:24 21:5 23:6 23:9	23:1 29:14	25:15	27:23	28:1	booth	19]	39:3	78:5	78:8	78:10	- 1
47:16 66:24	72:20 80:11	29:19 30:6	32:3	28:10	28:12	28:22	39:6	43:20	43:21	78:17	79:2	79:4	- 1
73:1 75:14 118:16 120:9	ου. I I	32:7 32:11	32:15	29:10 30:5	29:11 31:4	29:12 34:4	53:9	53:15	53:21 60:20	79:15 81:5	79:21 81:17	81:3 81:24	j
awareness [2]	47:9	32:18 33:6	33:12	30:3	39:17	39:25	60:3 60:22	60:18 60:25	60:20 61:8	82:6	82:15	82:16	1
122:21		33:13 34:10 39:15 39:16	39:10 39:21	40:16	41:6	44:10	61:19	62:3	62:6	83:2	83:9	83:18	ļ
away [4] 8:9	8:10	39:22 41:3	41:5	45:18	45:21	47:2	87:3	87:5	87:10	84:8	84:10	84:19 89:18	
29:25 71:15		41:15 44:18	44:24	47:3 48:16	47:7 52:25	48:8 55:1	booths		56:24	84:21	85:4 102:1	89:18 102:4	j
B (2) 71:1	71:2	45:23 46:9	46:10	64:9	64:15	64:21	57:2	57:4		cardbo			į
71:7	70.0	46:19 46:19 47:17 48:23	47:10 49:3	65:24	66:1	66:7	border	[1]	91:16	22:24	26:7	28:15	
15 14 17	. 70:3	49:6 51:18	51:20	67:17	67:24	67:24	92:8	B (C)	04.16	28:16	28:22	30:24	ł
backing (2)	26:8	51:24 52:8	52:10	67:25	76:1	80:5 81:17	97:12	n (≋) 105:3	94:15 . 105:12	31:3	31:7	55:7 71:14	ļ
104:18	100:23	52:13 52:18	52:20	80:25 81:23	81:10 82:5	81:17 84:9		105:3		70:2	70:17 76:19		ľ
Bair [32] 87:5 109:16 110:13		54:2 54:17		84:17	88:9	88:12	107:16	i		71:15 84:22	70.19	U7.44	Ì
111:6 111:21	112:12	54:20 54:23 55:25 56:1	55:13 56:4	101:3	101:12	2 105:20	break	(9)	30:8	cards	7221	26:21	. [
112:18 113:3	113:20	56:12 57:19	57:22			8 106:22	20.9	40-16	54:8	26:23	27:3	27:11	
114:19 115:10	115:13	57:25 58:1	58:5	109:8			55:10	55:18	85:17	27:13	27:13		
115:20 116:24	117:3	58:8 61:11		blow				1 123:24		27:19	30:4 59:24	59:16 63:21	
117:6 117:13 117:22 117:25	118:2	62:25 63:7 63:18 64:3	63:15 64:24	blowe		5:24 45:7	breath	_	20:5 25:6	59:21 63:24	59:24 64:10	64.7	
118:7 118:19	119:11	65:7 65:25		45:4 45:15	45:5 47:22	45:7	brief ( 25:8	13] 37:20		76:3	81:9	84:7	÷ ,
119:17 120:4	120:22	67:8 68:13	69:2	blowe		4:20	54:12	70:10	85:11	96:8	96:9	102:9	
122:12 122:15	122:19	69:3 69:14	70:23		2) 43:24		88:25	89:12		carefu	ılly(i)	120:2	1
											l'n	dex Pag	e 2
KIRBY A. K	ENNE	DY & ASSO	CIATE	S (612	:)922-	1955						, ka	
											1.07		

						•					23.3-
RANDY ARN	IOLD			Condense	:It™					Casc -	design
Case [2] 1:8	116:21	31:7 54:1	66:5	conditioning (	1		7:3 1	27:14	cutting	4]	30:16
	10:21	70:17 71:5	71:8	114:1		127:16			30:21	66:9	101:17
	11:14	85:3		confidential (1	0]	counsel		4:16		13:23	13:24
11:17 11:19	11:21	circuits (1)	20:5		110:8			9:2	14:2	17:22	87:4
11:23		circular [7]	29:21	117:13 117:18	117:25			0:14 119:22		118:9	119:4
caught (1)	113:9	53:3 54:6	55:15	119:11 119:13 126:3	122:19		3:23 I 27:15 I		119:16		120: <del>9</del>
CELINE	2:2	56:5 76:20	76:20		97:6	counting		52:1	D.C (1)		Į
center (5)	1:19	Cities [2]	15:5	confirm(1)				1:16			1
27:16 38:18	76:20	123:4	1	conform (1)	21:5	County (1	27:7	1:10	dad (5)	13:25	14:5
127:5		City (1) 15:4		connected (1)	52:9	couple 12		60:19	date [4]	1.4	.38:14
certain (52)	7:4	claims (1)	87:18	connection [21	8:13	121:9				87:24	-36:19
8:20 13:17	15:3	Clapp (2)	2:13	8:13- 16:4 22:4 22:8	17:5 27:20	COURSE [2]		42-16	Dated		126:23
15:6 16:8	19:20 35:11	3:2		29:9 52:12	52:15	60:16	ı		Dave (2)		14:3
27:12 33:11 35:13 36:9	40:8	cleaned [1]	17:22	58:8 66:1	69:13	court (11)		1:1	days [6]		37:14
41:14 42:19	47:20	clear (2) 96:7	98:22	75:24 77:9	80:25		2:15	38:3		53:6	60:16
49:7 57:24	59:6	clinical [3]	42:7	85:19 102:1	102:5			85:25	60:19		00.10
59:12 60:1	60:9	112:11 112:18		111:8 112:12			08:13	109:18	decide	31	6:17
60:10 60:12	60:14	clinician (2)	7:4	consider [9]	22:16	127:24			19:21	49:11	
60:23 63:25	65:9 72:23	72:1		74:25 76:19 88:4 103:7	87:22 105:6	COVET		15:10	decided	[19]	12:24
65:10 71:21 72:24 75:16	79:18	clinicians (10)	64:6	88:4 103:7 117:5 117:6	103:0			21:22 51:15	13:2	13:5	18:6
82:9 82:13	82:22	64:8 64:13	64:18	consideration	(33			90:15	57:18	62:17	64:2
83:20 84:2	84:11	64:24 65:6	65:11 109:10	6:14 18:12	[2]			98:22	66:25	72:6	
84:20 85:7	96:17	65:20 73:5		consideration	e (1)	100:25			decisio	D [2]	12:7
101:11 103:24	104:13	close (2) 95:12	95:16	21:11 32:5	81:4	covering		20:8	12:18		
106:11 107:20	107:24	closed(1)	84:22	considered (2)			106:25		decreas		80:24
109:14 114:3	115:14	closer (4)	17:8	114:19.	70.24	COVCES		63:24	Defend		1:11
certainly (3)	6:16	17:8 17:10 68:5 94:25	68:5	considering (	1 19:10	create (1)	•	15:10	2:11	86:16	
43:6 119:8		1	95:1	19:16 19:17		cross (1)			Define	: -	105:22
Certificate [1]		closest (1)		constitute [2]	85:20	Cross-E	•	etion	define	1 (ոչ	34:7
certify [1]	126:5	closing [3]	92:11	114:23	05.20		2:18	3:21	deflate	d (1)	52:18
cetera (1)	26:4	97:21 99:18		constructed (	1 26:2	crosses		21:17	degree	[1]	28:13
change (21)	33:22	cloudy [1]	96:6	54:20 91:6	,	current		89:21	demon	strate	[2]
33:25 34:1	42:15	cloverleaf (1)	78:22	construction	(2)	110:10	[2]	07.41	51:23	51:25	•
42:22 43:5	62:18	cluttered (3)	6:7	70:1 88:19		curvatu	P# 711	81:21	demon	stratio	DS [2]
62:25 63:6 68:8 68:13	67:24 . 69:4	6:19 7:10		consumer (i)	56:4	1 .		99:15	61:4	61:6	• •
68:8 68:13 70:8 74:14	74:16	code [1] 118:15		continue [2]	70:20	curved	-		depart	ment (s	1 41:24
76:1 79:20	81:9	collectin	56:24	111:12	70.20	custom		31:22	51:11	73:7	73:9
126:8 126:11		collecting (1)	114:5	continued (1)	111:14		32:2 66:6	32:7 . 71:13	74:8	119:25	120:9
changed (s)	27:10	collects (1)	114:4	Continuing			72:17	85:4	120:23		
42:13 42:24	43:1	color (2) 49:16	86:2	38:9 54:14	70:12	101:18		••••	depict		66:2
43:5 88:10	107:12	Columbia	2:4	70:15 85:15	89:14	custom	TS (23)	28:14	81:24	82:17	
110:16		comfortable			108:22	32:11	33:22	42:1	depose		3:18
changes (11)	47:16	coming (3)	15:5	124:3		42:11	46:20	47:7	deposi		
48:22 63:11	68:12	15:8 92:6	13.3	continuous (1	108:5	47:10	47:19	47:23	1:15	2:19	25:16
68:25 73:19 74:8 78:16	73:23 83:6	commencing	***	contribution	S [1]	48:16	48:25	49:3 58:5	38:1 49:20	38:13 49:22	38:14 67:13
74:8 78:16 84:3	83:0	1:19	(1)	111:19		49:6	53:17 61:8	63:20	79:24	85:19	86:1
	74:2	communicate	• (1)	convective ()	ງ 10:3	58:24 67:15	71:9	72:10	86:11	108:1	
changing [1]		73:19	- (-)	12:8 12:19		72:13		72	110:2	124:1	1 124:21
characteristic	[2]	company [6]	110:18	Convectively	Y (13	custom	ers' m	33:20	125:1	126:2	
7 ***		117:7 122:2:		9:25		cut [16]		28:3	127:4	127:1	1 127:15
characteristic	3 [2]	123:1 123:4		conversation	IS [1]	28:8	28:15	29:15	127:17	_	
		complete (1)	84:6	117:2		29:21	29:25	30:13	descri	pe (3)	84:7
characterizati 71:23 88:20	OB [2]	completed		copies [1]	127:15	55:22	55:24	56:5	95:20		4
	43:11	28:21 33:5	33:13	corners (1)	79:5	66:6	66:17	71:8		peq (a)	78:5 80:1 <b>6</b>
charge [2] 58:24	43:11	34:9		correct (19)	3:25	85:4	101:10		78:6	78:9	80:10
	127:15	completion	11 126:1	24:15 65:8	91:25	cut-out		19:17	119:16		. 63.3
charged (1)		comport [1]	69:11	97:18 97:24		19:22	20:1	20:13		bing (2	ŋ 52:3
checking (2)	114:8	concerned		98:17 98:23	99:6	20:15	20:20	20:22	52:19	:	m, 6.6
124:15		106:15	7.17	99:11 99:15		21:1	21:4 70:16	55:15 91:24	descri	ption	(3) 3:3
chest (3) 10:22	11:21		125.2	99:25 100:8		55:16 92:2	92:13	93:1	5:9		4.14
11:23		concluded		104:19 105:1		93:6	93:25	94:1	design 6:15	6:18	6:15 8:2
chief [1] 121:11		conclusion (	1 8/:1/	correspond	2] 86:3	94:2	94:4	96:14	12:8	12:19	
choiœ (ι)	76:11		<b>6</b> (5)	86:6		97:12	98:5	98:6	13:11	14:3	14.5
Cincinnati (1)	56:20	condensatio		corresponde	nce [1]	99:14			14:13	14:21	14:24
circle (1)	31:3	114:4 114:6		115:25							100

Circle (a) 31:3 114:4 114:6 115:25

KIRBY A. KENNEDY & ASSOCIATES (612)922-1955

index Page

RANDY ARNOLD	•	Condenselt™		designed - exter	9
15:16 16:10 19:1	89:2 90:4 97:6	down (4) 15:7	effort(1) 121:10	78:10	<b>ن</b> ا
19:11 19:12 21:25	101:14 120:8	20:24 21:21 107:25	either [12] 10:23	evidenced (1) 127:18	1
		Dr [31] 4:21 4:24	21:18 23:15 37:13	example [3] 69:23	į
23:25 24:3 24:7	dimension (1) 76:3	5:20 6:4 7:1	37:16 44:18 45:19	88:3 91:18	1 '
24:25 25:13 32:5		7:20 8:21 10:14	51:19 63:22 71:14	except[1] 126:7	1
[ 32.0 32.17 33.0 ]		11:3 11:18 11:22	74:17 79:12	excess [2] 92:11	
1	direction (1) 127:11	13:22 14:11 15:14	cmployœ (2) 13:23	92:18	
39:19 39:25 41:6 45:7 46:2 46:16	directly [2] 30:20	15:19 18:18 19:2 20:3 63:3 65:16	121:20	exchanger(i) 114:4	- 1
46:18 46:20 47:13	76:21 disagree m 71:23	87:4 113:6 115:6	employees [7] 13:24	Excuse [1] 70:7	- 1
47:17 47:18 48:23	disagree [2] 71:23 88:24	115:16 115:19 115:22	113:2 113:9 115:20	executed [1] 127:18	1
48:24 51:20 62:18	disassembling (5)	115:22 116:22 117:1	enclosing (1)" 109:6	exercise (1) 124:22	
04.4 . 05.7	1 113-10 113-18 114-19 1	119:8 122:18	enclosing [1] 109:6 end [28] 7:3 21:18	exercise (1) 124:22 exhibit (6) 25:19	.
68:12 68:16 73:19 73:23 74:25 75:3	114:23 115:5	drape (8) 20:24	30:10 91:25 92:2	27:17 29:4 38:1	-
	discuss (4) 7:7	96:8 105:7 105:8 105:10 107:19 109:1	93:5 93:9 93:10	38:15 38:17 38:18	- 1
75:11 75:15 75:15	7:12 10:17 115:15	105:10 107:19 109:1 109:4	93:10 93:11 93:12	39:11 41:5 41:6	ł
75:20 75:21 75:24	discussed [12] 6:20	drapes (3) 18:11	93:12 94:7 94:24	41:16 45:4 45:5	1
76:4 76:10 78:4	7:15 10:15 10:18	18:16 19:11	97:9 97:21 98:5 99:4 99:18 103:20	45:10 45:24 46:11 46:19 47:14 47:23	1
78:13 79:20 80:4 80:15 80:17 80:20	11:9 13:8 18:22	draping (5) 18:17	99:4 99:18 103:20 104:3 104:16 104:22.	48:24 49:9 49:11	١
80:15 80:17 80:20 81:24 82:6 82:16	20:3 29:7 74:9 97:22 113:19	18:23 19:14 21:2	106:24 107:2 108:1	49:20 49:22 50:2	ı
83:1 83:5 83:18	discussing [6] 13:10	21:16	108:5 124:18	50:2 51:21 52:8	1
84:12 84:19 89:21	discussing [6] 13:10   16:13   18:17   19:14	draw (1) 78:24	ends [4] 92:12 95:11	56:16 56:18 56:20	I
89:21 89:22 94:12	25:13 74:7	drawing [1] 69:7	95:12 98:14 99:10	56:22 57:15 58:12 58:21 62:19 62:19	Į
96:8 96:10 96:12	discussion [12] 25:7	drawings [14] 8:6	103:3	58:21 62:19 62:19 63:18 67:13 69:9	1
109:1 118:19	37:17 37:21 38:8	8:8 8:12 18:15	engineer [5] 73:10	69:22 70:1 70:16	١
designed (4) 31:23 54:23 54:25 68:15	70:11 79:22 85:12	75:14 75:15 75:19	83:8 83:9 83:12	75:4 78:6 78:9	ı
54:23 54:25 68:15 84:10 84:15	85:18 89:13 96:25	77:6 77:8 77:8 83:1 83:5 83:15	119:4	79:21 79:23 79:24	ł
designing (12) 4:19	100:14 108:21	83:1 83:5 83:15 83:18	engineering (1) 74:9	80:4 80:16 81:6	1
5:1 6:11 9:14	discussions [19]	drew (1) 124:12	cngincers [2] 118:20	81:25 82:6 82:17 83:2 83:10 83:19	
9:19 31:21 32:1	4:18 5:22 6:3 6:16 6:18 6:24	drew (1) 124:12 drink (1) 108:15	121:11	83:2 83:10 83:19 83:25 84:1 86:11	
53:24 53:25 69:1	6:16 6:18 6:24 7:19 8:24 9:1		entire [4] 87:3 120:2 120:5 120:7	87:1 100:19 100:19	9
77:17 77:21	10:13 19:2 23:3			105:17 108:10 108:1	
designs [17] 13:1	23:5 32:9 67:3	dual (22) 40:15 49:2 67:7 67:16 67:25	30-11110-111	124:12 124:14	I
13:8 13:14 15:9	74:1 75:6 116:23	67:7 67:16 67:25 68:14 69:2 69:13	entrance [22] 6:21	exhibits [14] 2:19	ŀ
16:13 18:11 18:13 19:15 34:19 34:20	122:17	68:14 69:2 69:13   72:7 72:21 73:4	6:25 22:1 22:4 22:7 22:20 22:25	2:24 2:25 37:25	
19:15 34:19 34:20 34:20 34:22 34:25	display (5) 42:14	74:3 75:7 75:14	22:25 23:6 23:17	38:13 38:13 38:19	
34:20 34:22 34:25 34:25 77:17 83:23	42:15 87:2 87:4	75:20 75:24 76:25	23:19 23:25 25:14	53:16 53:19 56:15 66:2 85:18 85:19	
83:25	87:9	77:17 78:10 87:5.	25:17 25:23 28:23	66:2 85:18 85:19 86:2	١
designwise [1] 63:6	distinguishing [1]	87:18 89:19	29:20 29:21 29:24	existed (4) 25:15	, 1
desire(i) 15:10	distribute (1) 33:22	duly [3] 3:17 127:7	31:23 32:6 53:24	25:17 25:24 27:15	
desired [1] 126:8	distribute [1] 33:22	127:9	entrances [2] 22:11	existence (1) 28:10	
detached [1] 79:14	distributed [3] 41:25	dummies [2] 106:7	63:8	29:8 120:5	ı
79:15		106:9	entries [2] 7:13	existing [1] 19:3	ı
detail(1) 81:14	distributing (2) 50:22	during [34] 6:1	7:21	exited (2) 105:3	14
determine   19:25	59:21 DISTRICT on 1:1	7:20 8:5 12:7 12:18 13:2 13:13	entry (5) 7:13 7:21	105:18	
	DISTRICT (2) 1:1	12:18 13:2 13:13 14:7 14:10 14:24	62:19 72:4 83:23	exits [1] 105:12	
determined (1) 18:5	DIVISION (1-1-1	17:4 17:5 18:20	environment [1]	experience [2] 9:19	
develop (1) 13:14	DIVISION (1) 1:3	19:18 22:11 23:9	114:2 ,	31:13	
developed (1) 13:2	document [2] 67:12	23:15 25:16 26:22	equipment [7] 5:11		5
developing [1] 22:13	86:15	27:20 29:10 29:13	6:7 6:9 6:12 7:11 9:12 20:6	explain [2] 69:25	-
development [10]	documents (1) 8:13	30:5 42:16 45:15	1		
4:10 8.5 16:21	doesn't(1) 88:16	45:18 45:21 49:16	Ernst (2) 2:3		
17:6 111:10 111:13	Don (1) 118:21	53:21 56:15 85:17 87:3 120:7 122:11	3:8 ESQUIRE <sub>(3) 2:2</sub>	explanation [2] 70:15	_
111:15 120:7 121:10	dope (13) 4:16	1	ESQUIRE (9) 2:2	70:20 explanations [2]	
122:11 Diagram (1) 2:22	9:11 9:23 55:19	Dykins (1) 43:22 62:7 62:13	2:3 2:8 essentially [2] 24:3	61:10 62:2	
Diagram (1) 2:22	66:7 66:10 66:10	1'	65:25 24:3	extended [2] 103:2	20
diameter (2) 81:6	66:11 66:13 66:22 86:1 101:17 101:18	carly (5) 8:2 19:6 67:21 73:23 111:10		105:3	-
81:10	1	EASTERN [2] 1:2		extending (a) 93:5	
difference (2) . 81:15	DONNELLY (1)	1:3	ct [1] 26:4	94:23 95:6 98:8	
106:20		1 2	evaporating [1] 114:6	98:14 99:25 103:	
differences [9] 47:1	dotted (1) 71:5	edge [4] 97:12 102:19	EASDOLUTION (e) 113:51	104:22	
00.7	double [1] 78:17		113:23 114:5 114:9	extends [1] 97:1	
93:18 95:18 102:8 102:12 107:9	doubt [1] 33:9	edges [2] 102:21	1		25
	Doug [2] 43:22		evenly [1] 21:12	extent (1) 117:	
different (9) 15:9 40:14 77:2 81:12	62:7	effectively (3) 9:15	eventually [2] 46:20	11.	
TU.17 11.6 01.14	1	1		Index Po	<u> </u>
			4.5	INDAY Do	

KIRBY A. KENNEDY & ASSOCIATES (612)922-1955

RANDY ARN				Condense				exterior - in	stances
exterior (2)		final (1) 46:2		fresh (3) 42:13 43:16		heavy (I)	26:7 37:21	10CE [2] 16:7	111:16
117:12		finalized [11] 23:20 23:23	23:9 24:10	front(10)	51:6	held [10] 25:7 38:8 70:11	85:12		87:6 90:18
extra [4] 91:18 92:6 92:8	91:19	24:22 24:23	25:14	70:5 70:25	89:19	86:24 89:13	96:25	101:25	90:18
extreme (1)	76:4	25:24 31:23	39:18	95:19 100:23	101:6	100:14 108:21		identification	(4)
extremities (2)		69:12	}	101:25 102:13	107:10	help (4) 13:15	14:7	3:6 38:2	49:23
20:23	10.0	fine (s) 49:10		full (2) 18:9	21:20	14:17 122:4		79:25 86:12	108:12
eyes [3] 109:21	110:3	86:5 86:9		function (2)	88:15	helped (5) 14:6 14:9	13:16 53:16	identified (2)	39:22
110:9		finger (2)	30:11	88:16		14:6 14:9 108:25	33.10	identify()	39:10
fabric (1)	95:22	31:16 Firm (2) 2:3	2:8	future (1)	120:14 76:8	Hennepin ()	1:17	identity (1)	27:6
fabricating [2]	14:14	firms (i)		gain (2) 11:1	113:2	127:3 127:7		IDS (2) 1:19	127:5
14:16		first (4)) 3:17	4:3	gained (1)	6:5	hereby (1)"	126:5	illustrations	
faces (1) 70:5		4:4 4:4	4:6	gas (2) 5:10	56:18	himself (1)	14:11	11:4	•
facilitate (1)	21:1 58:14	9:13 10:8	11:13	Gaymar(1) general (2)	7:19	hold (1) 102:23		impression (1)	9:13
31:22 32:7 69:4 76:11	79:22	15:22 16:3	16:21	7:19	7.17	holding (2)	91:17	improperly [1]	113:2
103:14		19:7 33:2 36:14 36:18	36:8 36:24	generally (4)	6:7	97:20		IBC [4] 1:5	1:10
facilitated (2)	21:16	37:5 37:8	45:12	7:18 12:24	74:5	hole [19] 27:16 28:8 28:15	28:3 28:16	3:9 86:16	
74:17		47:3 47:3	47:7	83:14 83:16		28:23 71:8	78:20	include (4)	19:22
facilitates (1)	20:23	47:9 47:21 48:7 48:15	47:22 50:4	generate (1)	59:16	78:23 84:21		20:1 20:14 included[1]	21:25 29:13
facilitating (2) 32:10	32:2	50:7 50:10	58:5	gentleman [1]		holes (1) 105:17		incorporated	
facility (1)	113:10	69:16 86:21	110:22	given (3) 117:15 127:12	117:10	hook (1) 30:6		23:20 24:9	62:25
fact (s) 6:10	32:13	112:6 117:5	121:6 127:8	glued (1)	90:24	hose [112]	7:5	78:5 80:5	80:7
34:22 43:4	81:11	122:21 123:2	78:23	goes (1) 24:14	70.24	26:15 26:18 26:23 27:3	26:21 27:6	81:24 83:24	
factor(1)	67:4	fits [2] 78:19	78:23 111:23	goings (1)	9:16	26:23 27:3 27:11 27:13	27:13	incorporating	[1]
facts [1] 116:21		five [2] 42:20 flag [2] 55:5	68:15	good (2) 3:23	42:13	27:14 27:19	27:22	75:25 indentation (1	1.00.4
fair (1) 88:20		flags (5) 26:16	26:17	Greg [2] 119:1	119:3	28:15 29:8	29:13	indented (1)	99:11
Fairly [1]	106:19	26:20 26:21	26:23	guess [14]	7:9	29:14 29:20 30:6 30:7	30:4 30:10	independent	
fall [18] 23:12	23:13	flex [1] 79:6		17:1 17:19	17:23	30:19 30:20	30:23	39:1	141
23:15 23:16	23:25	flexes [2]	78:22	18:1 19:5	23:11	31:3 31:14	31:15	INDEX	2:17
24:10 25:2 25:24 26:23	25:15 27:15	79:7		27:8 41:10 43:8 52:17	43:6 61:1	31:16 31:23	32:2 52:12	indicate [4]	73:23
25:24 26:23 27:21 29:11	29:13	folded (2)	71:1	118:4	01.1	32:2 52:9 52:15 52:21	52:12	74:11 118:13	118:17
30:5 32:13	32:20	78:18		guessing (2)	61:20	53:2 53:3	54:1	indicated (13)	
34:3		follow (3)	21:14	61:22		54:5 54:6	54:19	50:16 73:3	85:23
familiar [4]	10:2	32:4 34:5	23:22	guidance (1)	5:2	54:21 55:1 55:5 55:6	55:3 55:11	97:22 98:7 98:16 99:2	98:13 99:13
	112:11	following (3) 109:19 110:1	23:22	half (6) 71:1	7.1:2	55:15 55:17	56:5	99:17 100:5	119:11
familiarizing	[1]	follows [2]	3:18	71:2 77:15	82:23	58:8 58:12	58:13	individuals	2] 108:25
far (4) 23:13	101:15	126:7	•	83:5	118:21	58:14 63:14	63:20	116:23	
105:17 106:15	101.15	foot [15] 93:10	93:11	Hamid (2)	116.21	63:22 63:24 64:9 65:7	64:3 65:25	inflate [2]	52:1
fast[1] 17:1		93:12 93:12	94:24	Hamlin (2)	119:2	66:1 66:4	66:6	90:1	
favorin	76:20	99:3 99:18 105:6 105:8	104:22 105:10	119:3		66:18 66:18	68:15	inflated [7]	52:5 105:21
favorable	5:21	105:6 105:8		hand (11)	36:5	68:16 69:1	69:12	52:6 52:20 105:24 105:2	
feature (4)	90:2	109:4		42:11 43:14	43:18	69:12 69:21 74:17 75:23	70:1 76:3	infringemen	
90:2 106:16	106:17	foregoing (1)	126:6	67:12 86:15	90:14	76:15 76:18		87:7 87:11	87:22
February (4)	1:18	forgotten [1]	27:9	103:21 118:23 127:20	118:45	78:3 78:5	78:8	87:25	
3:4 125:1	127:5	form [4] 25:17	106:5	Hand-Drawn	rt)	78:9 79:21		infringes (1)	87:19
feedback m	64:5	106:10 106:13		2:22		81:3 81:5 81:12 81:15	81:9 81:24	initial (1)	96:12
64:13 64:17 65:15 73:4	65:11 109:9	formed (1)	96:4	hardly [1]	77:5	82:6 82:15		inlet [1] 124:1	
feet (4) 10:24	106:25	forwarded [1]		head (23)	19:18	83:2 83:9	83:18	inner (2) 31:3	31:7
107:3 109:7	100.40	foundation		20:8 21:22	91:25	84:7 84:8	84:10	input (1) 16:10	)
fellow (1)	13:25	28:18 28:25		92:2 92:6	92:13	85:4 96:8 101:6 101:2	96:9 14 102:1	insert (5)	54:19
felt (5) 6:7	6:8	35:10 41:20 44:7 46:23		93:1 93:5 95:16 96:7	93:9 96:16	102:4 102:5		54:20 55:1	55:17
18:8 20:6	32:14	48:13 59:11		97:9 97:12	97:21	hospital (1)	5:15	101.5	76:21
few (2) 11:14	97:5	71:20 74:20	79:17	98:5 98:22	103:4	hospitals [1]		inserted (1)	31:14
few-minute [		82:2 82:12		103:20 104:2	104:16	Hugger [2]	87:5	inserting (3) 32:2 58:14	
field (9) 20:17	20:19	85:6 87:13		107:2		100:24	J7.J	insertion (1)	55:9
21:21		113:25 114:1		beading (1)	67:14	humidity (1)	114:2	inside (1)	51:19
Figg (2) 2:3	3:8	four: 111:2		hear.[i] 113:5		hundred (5)	17:9	79:8 112:	
file [1] 8:2		frame (4)	24:8	heard [3]	113:1	17:10 35:1:		instance (1)	12:24
Filing (1)	127:19	67:8 67:17		115:18 116:2		60:12		instances (2)	
				heat as 114:4					

Filing (1) 127:19 67:8 67:17 73:24 heat (1) 114:4

KIRBY A. KENNEDY & ASSOCIATES (612)922-1955

RANDY ARNOLD		Condenselt™		instead - mind
7:7	87:20 109:16 127:4	107:16	23:24 25:15 32:17	73:16 73:20 73:21
instead [1] 95:24		layout [7] 5:6	33:12 33:13 34:4 34:15 39:14 41:3	74:8
institution [1] 112:21	2:3 2:18 2:25 3:7 3:7 3:8	5:9 5:16 7:25 8:19 8:22 15:16	41.4 44.10 45.19	marketing's [1] 73:19
instructed (2) 72:1	3:22 11:12 12:12	lead (3) 59:16 59:21	45:23 46:19 47:2	mass (1) 33:21 mated (1) 71:1
109:18	12:17 16:17 16:19	59:24	47.3 47.0 77.10	material (44) 29:14
instructions (2) 71:25	21:10 24:9 24:15	learn (1) 10:11	47:17 48:7 55:13 56:11 57:19 57:21	29:20 91:18 91:20
72:2	24:18 24:20 25:4 25:12 26:10 28:20	least [1] 20:7	66:7 76:4 80:24	92:6 92:8 92:11
instruments (1) 103:15 intended (4) 54:19	29:2 29:18 30:3	Jeave [1] 120:14	94:24 94:24 95:6	92:16 92:18 92:23
intended [4] 54:19 55:10 55:17 79:9	31:12 34:14 34:18	left [11] 6:12 6:13	95:23 100:24 100:25 102:1 102:13" 102:17	92:25 93:5 93:13 93:20 93:21 95:23
intent [1] 63:23	35:12 35:18 35:22	7:11 38:16 39:12	102:19 107:10 109:1	97:8 97:9 97:10
intention [2] 63:17	36:2 36:4 37:4 . 37:17 37:24 38:4	39:14 41:4 41:5 93:6 98:6 98:15	lowering (1) 76:1	97:11 97:13 97:13
63:19	38:11 40:5 40:9		lowest (1) 95:25	97:13 97:21 97:22 97:23 98:4 98:5
interest [4] 123:4	40:13 40:22 41:2	left-hand (2) 6:9 7:3	lunch (1) 85:13	97:23 98:4 98:5 98:6 98:8 98:13
123:10 123:13 123:19	41:22 42:5 44:9 44:22 45:3 46:25	legal (1) 117:9	lying (1) 12:5	98:14 98:17 99:3
interested (2) 53:18	44:22 45:3 46:25 48:2 48:6 48:11	legs [1] 10:24	M [1] 2:2	99:18 99:24 102:17
127:13	48:14 48:19 48:21	length(1) 81:18	machine (3) 6:5	102:19 102:20 102:24 103:12 106:21 106:24
interface [5] 5:7 8:25 9:5 9:8	49:8 49:12 49:15	less (3) 76:2 81:21	7:5 66:10	107:1
10:19	49:19 49:25 54:16 59:7 59:13 66:23	96:11	machinery [1] 14:1	materials [2] 26:2
interfere (1) 9:16	70:14 71:18 71:22	level (1) 114:2	machines (1) 5:11	107:12
interrupt [1] 70:8	74:22 79:19 80:2	lie [1] 21:12	45:12 121:12	matter (3) 3:16
intraoperatively [1]	82:4 82:14 85:2	Linda (2) 2:8	maintain [1] 11:2	116:6 124:9
10:1	85:17 86:6 86:10 86:14 87:15 89:9	3:10	maintained (1) 87:2	mattress [3] 10:5
introduce (1) 3:5	89:16 90:8 90:10	line [14] 4:7 4:12 4:14 4:16 4:19	maintaining (1) 109:7	10:9 10:11 mcan [17] 9:7
introduced [1] 84:16	90:12 94:22 96:21	5:1 13:7 14:17	majority (2) 7:2   64:6	20:22 21:15 24:17
introducing (1) 33:18	97:3 97:17 98:3 98:12 98:20 99:1	71:1 71:5 71:6	Mallinckrodt(21)	29:20 33:16 33:21
invented [1] 87:20	98:12 98:20 99:1 99:9 99:23 100:4	81:18 84:9 84:16	1:5 3:8 56:22	34:25 51:25 53:2
invention (1) 87:24	100:11 100:17 100:21	126:8 126:11	57:7 72:21 73:12	53:4 61:7 69:4 69:18 79:15 80:12
involved [9] 62:24	103:11 108:9 108:16	liner [4] 26:8 26:11 70:22 70:25	87:6 87:11 87:18 113:2 113:9 115:19	88:16
63:2 67:23 68:16 84:12 84:19 112:17	108:24 110:4 110:12 111:5 112:4 114:7	Listen [1] 67:15	116:13 116:16 116:24	means [9] 20:17
117:19 120:2	114:16 114:22 115:2	literature [2] 10:14	117:2 122:21 123:1	32:1 58:13 94:6
involvement [1]	116:11 117:11 117:16	56:24	123:3 123:13 123:16	104:2 104:5 105:23 109:6 114:5
120:2	119:22 120:6 120:13	load (1) 122:4	Mallinckrodt's [4]   87:21   87:24   123:9	meant [2] 55:9
inward(1) 103:20	120:17 120:20 121:2 123:23 124:5 124:17	loaded [2] 122:6	87:21 87:24 123:9 123:19	113:17
irrelevant(1) 81:19	Kurz. (1) 2:15	122:15	manufacture [2]	medical [10] 1:5
issue (1) 122:18	label [1] 79:22	located [2] 119:17	32:15 121:10	1:10 3:9 3:11
itself (1) 22:20 23:17	labeled (1) 110:2	119:24	manufactured (5)	9:20 10:10 10:12
30:10	labeling [2] 76:8	location [1] 118:7	4:8 26:3 26:3	86:16 87:2 118:9
J <sub>[2]</sub> 2:8 87:2	119:10	locations [1] 28:1	26:22 26:23	Medical's[1] 87:18
JAS (1) 126:24	lack [25] 26:5 28:17	LOD (1) 1:8	manufacturer (3) 27:7 27:14 31:8	meet (3) 14:23 15:9
Jennifer (2) 1:16 : 127:24	28:24 29:16 35:9	loft [2] 76:1 80:25	27:7 27:14 31:8 manufacturers (1)	meeting [3] 16:12
JIMENEZ [1] 2:2	41:19 42:2 44:6 46:22 47:24 59:10	longer [2] 81:20 123:13	27:11	86:22 86:24
Judgment [1] 86:17	66:20 71:20 74:19	look 11018:12 18:11	manufactures (1)	memorandum (2)
Kansas (1) 15:4	79:16 82:1 82:11	57:14 61:7 67:14	27:3	86:16 86:20
keep [6] 8:2 20:16	84:24 85:5 87:12 103:9 113:24 114:13	75:17 75:18 88:25	manufacturing [2]	mention [1] 73:12
42:13 77:12 77:19	103:9 113:24 114:13 114:20 119:19	89:1 96:6	14:1 66:15 88:10	mentioned [2] 10:15
117:17	laid (1) 120:3	looked [12] 7:23 7:24 16:3 16:7	March [2] 4:2	81:4 merely (1) 115:4
keeping [1] 77:14	laminate (3) 95:23	17:21 19:7 19:8	1 .	
kept [1] 82:24	96:1 107:14	19:15 24:7 77:1	margin [1] 107:1 mark (4) 37:24 49:9	methods [i] 10:2 middle [i] 58:11
key (1) 118:15	larger (2) 90:21	100:18 106:17	86:2 100:17 100:17	magaz (.)
kind (2) 76:3 96:6	95:22	looking [16] 10:14	100:19	might (15) 5:12 7:4 9:5 10:23
knew [3] 112:13	last [4] 36:17 37:6	18:7 19:3 19:11 39:5 39:21 42:12	marked [16] 2:19	14:9 20:9 30:18
119:24 120:4 knife isi 30:16 30:17	82:23 83:5	42:13 58:15 70:16	25:19 38:2 38:12	65:20 90:21 96:11
knife [5] 30:16 30:17 31:16 55:20 66:12	launch (1) 13:7	76:7 76:10 76:16	38:13 38:19 49:20 49:23 50:2 57:15	96:16 107:20 119:2 119:6 123:22
knowing [2] 120:6	18 W (3) 1:18 2:3	87:16 91:5 96:10	67:12 79:25 85:19	migration (1) 20:18
120:8	lawsuits (1) 8:14	looks [1] 78:22	86:12 108:9 108:12	milky [1] 96:6
knowledge [4] 4:16	lav (1) 79:7	lower [49] 2:23 10:23 12:25 13:3	market (1) 25:1	mind (4) 6:11 24:22
23:19 72:3 114:24	layer (4) 76:2 95:21	18:4 18:8 18:13	marketing (s) 16:9	33:9 116:16
118:3 118:22	95:25 107:15 107:16	22:17 23:9 23:21	51:11 73:6 73:8	

RANDY ARNOLD	,	Condenselt™				Minneapolis - patient			
Minneapolis (4)	119:19 120:1 120:11	17:24 18:1		ober (2)	36:24 OF		3:9		
1:19 2:10 3:3	120:16 120:19 120:24	nozzle [28] 7:	13 86:		Of	ders (*) 3	3:19		
127:5	124:13 124:20	7:13 7:21 7:	21 off	[46] 25:4	25:5 4		5:20		
Minnesota (7) 1:17	name [4] 3:2 3:7	22:1 22:4 22	:7 25:	6 27:25 .			9:8		
1:19 2:10 3:4	110:10 110:16	22:10 22:25 23	:6 37:	19 37:20		9:14 59:19			
127:2 127:5 127:7	named (1) 13:25	23:16 23:19 23	38:		38:16 or	riginal (9) 2	1:14		
1 12/12		23:25 24:7 25	5:14   45:		70:8   3	6:2 48:19 4	19:14		
TITLE COMP (-1	names (1) 14:19		3:23 70:		85:8		36:1		
96:22	narrower [2] 21:17	30.7 32.0	2:7 85:		89:9	26:1 127:14			
minutes [1] 11:14	96:16		):8   89: 1:3   91:		91:20 94:10	riginally (1) 🧐	96:14		
mischaracterizes (1)	necessarily pp 30:15				95:16		35:24		
71:16	93:19	12422	رند ا دع.،		96:24	86:3 86:8	124:8		
MISSOURI (1) 1:2	necessary [2] 81:11			:21 99:18			32:22		
mistaken (1) 79:5	81:16		8:7 100	0:12 100:13			85:21		
model (24) 2:23	neck (3) 19:22 20:2		7.1   10-			86:24			
2:23 45:24 45:25	21:1	79:25 89:6 9	1:9   10	7:5 108:8			52:17		
46:10 46:11 46:12	need [5] 5:6 49:8	101:1 108:10 1		8:20 123:25		127:15 127:16			
57:16 57:19 57:22 58:2 58:4 58:7	74:17 75:23 89:7	124:14 126:8	off	er [2] 64:3		utcome [1]	127:13		
68:14 68:14 89:4	needed (1) 20:6			ice (II			13:22		
89:6 89:20 89:22	peeds (2) 20:4		6:12 off	ices (1)			112:8		
100:23 100:24 101:1	33:20	101:2 108:12	off	ficially (1)			121:13		
101:2 101:5	negative (1) 9:13	- tan ()	:21	en (2) 14:23		outstretched (2)	ì		
models (1) 45:11	negotiations [1]		:19	ce [7] 15:1	15:2	10:25 12:1	į		
66:4 80:15	110:18			5:2 71:12	79:10	W10 [2] 69:25	116:15		
moment [2] 57:14	never(2) 17:23		.10	3:21 124:21		2.C [1] 2:4	1		
100:20	43:3			C [57] 7:21	21:11	.m [1] 124:25	1		
monitor [1] 20:5	DCW [10] 9:10 9:22		2:17 21	1:20 22:15		schage (2)	89:18		
monitoring (2) 20:4	32:22 39:4 39:8			4:9 26:9	33:2	101:4	1		
21:23	68:15 68:16 69:1		8:8 38	8:14 38:16	38:17	ackages [1]	28:22		
month (s) 4:6	85:21 86:24	49:21 57:19 5		9:12 39:12	39:14	PACUITO	18:9		
15:2 16:25 68:5	next [7] 12:5 12:20	85:22 106:8 1		9:15 44:13	44.17	22:5 24:4	24:11		
68:10	49:20 79:22 79:23	oath (1) 127:7		4:24 52:9	52:21	28:10 29:10	29:12		
Morgan (1) 1:18	86:4 100:18	objection (42)		3:11 63:8 3:14 63:22	63:8 64:3	55:25 56:9	66:7		
morning (2) 3:23	nice [2] 49:16 96:15		14.4	3:14 63:22 4:6 64:14	64:18	page [14]	2:18		
53:16	non-woven (3) 95:24		رة ا 29:16 م	4:20 65:11	68:18	2:20 2:20	2:21		
most (s) 33:1 53:20	96:2 107:13	30	34:11   -	6:11 76:14	76:16	2:22 2:22	2:23		
94:24 94:25 95:2	nor(i) 127:13		35:20   <sub>7</sub> .	7:10 78:18	81:4	2:23 67:14	86:21		
95:7 103:20 118:7	normal (i) 83:4			6:4 87:21	87:23	87:16 126:8	126:11		
Motion [1] 86:17	pormally [1] 73:18		ها ۱۵۰مه	9:10 90:18	90:25	127:18			
mounted (2) 81:18	normothermia [5]		40.0	1:7 98:15	101:24	paper (4)	95:23		
81:20	2:21 2:21 11:2		ا ا ۱۰	02:9 102:21 07:13 108:25		95:25 107:14	107:14		
move [1] 89:8	49:21 85:22	59:10 66:20		12:17 112:19	113:10	paper-like (1)	70:2		
1201011	Northwest [1] 2:4		82:1	23:3		baragraph (2)	86:21		
1	Notary [2] 1:16		85:5	nes [3] 57:5	62:9	87:17			
()	127:6		,,,,,,	07:23	V2	parallel (1)	91:6		
16:15 21:7 24:8 24:16 26:5 28:17	notebook (3) 77:12		,	ngoing (1)	112:13	parameters (1)	5:2		
28:24 29:16 30:1	77:14 82:24	100:9 103:9		pen (s) 6:13		part (3) 33:1	56:14		
31:9 34:11 34:16	noted (1) 120:19			4:21 85:1	85:3	Tunii			
35:9 35:16 35:20	notes (1) 8:6 8:8		114.7		52:21	particular (4)	4:10		
37:1 40:2 40:7	8:12 77:16 77:19			pening [14] 53:25 56:5	58:8	19:15 20:24	96:5		
40:11 40:19 40:25	83:1 83:5 83:13	120:11 120:12		66:25 74:17	76:11	111:16 118:7			
41:19 42:2 44:6	83:18	120:24		76:11 76:21	79:2	particularly (	ւյ 7։17		
44:19 44:25 46:22 47:24 48:4 48:9	nothing [1] 127.9	objections (2)		79:3 79:5	101:6	67:14			
	Notice m 1:15	120:18		101:15		parties (1)	127:16		
48:13 48:17 49:10 49:13 49:18 59:4	127:19	objective (1)	33:4	penings [4]	22:1	parts [1] 97:6			
59:10 66:20 71:16	noticing [2] 126:1	obscured [1]		01:11 105:11	105:13	party (1) 127:15	;		
71:20 74:19 79:16	127:15	obtain [1]		perating [7]	5:6		36:24		
82:1 82:11 84:24	1	obvious (1)		5:10 5:23	6:19	past [3] 36:20 82:10	30.47		
85:5 85:8 86:5			30.13	9:17 10:4	74:16		87:7		
86:9 87:12 90:7	notwithstanding (1)	occasion (1)	117·2U I	perator (1)	3:3	patent (2) 87:11	01.1		
90:9 90:11 94:21	43:4	119:6 121:11	l_	pinion (1)	87:25	1	87:19		
97:15 97:25 98:9	now [16] 30:4 31:2	occasions [3]		88:12 116:1		patents (1)	9:5		
98:18 98:24 99:7	40:17 66:4 78:17 80:8 93:5 93:14	122.7		PPENHE		patient [23] 9:8 9:12	9:5 9:15		
99:21 100:2 100:9	95:19 95:20 96:10	occur[1]	123.0	2:9		10:20 10:25	15:10		
111:2 112:1 113:24	99:3 107:10 110:1	occurred (1)	112:12	pposed (4)	12:20	15:17 16:4	18:8		
114:13 114:20 114:25	111:25 116:19	occurring (2)	20:21	77:18 96:6	107:17	20:4 20:7	20:9		
1 1100 11014	1 1	1 112-15	l l			1			

114:13 114:20 114:25 111:25 116:19 occurring (2) 20:2 116:7 117:8 117:14 nowhere (3) 17:24 112:15

KIRBY A. KENNEDY & ASSOCIATES (612)922-1955

a	à			
RANDY ARNOLD		Condenseit™		patient's - recess
20:18 21:6 21:12	place [7] 6:8 9:11	75:21 75:24 76:25	produce [3] 19:4	77:8 77:20 77:23
21:18 94:7 94:17 103:14 104:6 104:10	23:5 79:12 106:14 112:17 118:8	76:25 77:10 77:17 77:18 78:10 87:5	33:22 124:16 produced (s) 35:3	prototyping [2] 19:4 24:25
104:19	placed [7] 5:11	87:18 89:19	35:6 40:1 40:16	protrude (1) 21:21
patient's [4] 21:22 21:23 103:4 109:7	5:24 6:5 6:12 100:23 106:7 106:9	portion [34] 12:14 20:1 20:13 20:15	41:7 42:9 46:6 51:1	provide [3] 62:19
21:23 103:4 109:7 patients (15) 5:7	placement (1) 22:13	20:20 20:21 20:23	producing (2) 46:3	103:15 109:6 Public [2] 1:16
8:25 9:3 9:25	placing (1) 103:15	21:1 21:17 22:20 22:25 31:3 53:3	46:4	127:6
10:3 10:16 11:5 11:8 11:18 11:22	Plaintiff (2) 1:6	54:6 63:14 70:16	product [72] 4:7 5:6 8:25 9:5	punch [2] 31:15
11:25 12:1 12:5	2:6  plant [1] 14:18	70:17 70:23 91:24 92:2 92:6 92:13	9:7 9:10 9:12	31:16   purport [1]   85:21
12:9 12:20 pediatric [2] 84:9	plastic [33] 29:24	93:1 94:23 95:4	9:14 9:23 10:20 13:7 33:19 34:2	purpose [2] 103:12
84:16	29:25 30:9 30:12 30:13 30:17 30:20	95:6 95:11 95:15 96:4 98:5 99:11	42:11 42:12 42:13	103:16
peel [3] 94:16 104:14	30:13 30:17 30:20 31:15 31:17 52:24	100:7 104:22 104:25	42:14 42:14 42:16 42:22 43:7 43:12	pursuant (i) 1:15
104:18 pcel-off(3) 26:8	54:1 54:4 54:6	105:1 109:19 110:1 126:3	43:16 43:18 53:18	push (2) 30:7 71:14 pushing (2) 30:24
26:11 100:7	55:11 55:14 55:18 56:6 58:14 66:5	portions [4] 19:17	57:11 61:5 61:7 63:21 75:18 83:7	32:11
peeled (4) 27:25	70:24 76:2 76:22 78:19 78:21 90:13	19:22 21:4 21:19	83:13 87:6 87:9	put[11] 6:8 6:20 6:25 23:6 28:22
70:22 94:10 104:10 pen [1] 79:1	90:15 95:23 98:22	ports (7) 35:1 40:1 64:20 64:25 74:24	109:15 110:5 110:19 110:20 110:22 111:9	6:25 23:6 28:22 43:7 49:11 49:12
people (11) 43:20	101:11 101:15 101:17	75:3 77:10	111:22 112:6 112:12	86:3 110:7 121:18
52:1 52:3 60:2	107:14   107:17   Plaza [1]   2:9	position [4] 10:16 10:24 11:18 11:22	112:22 113:3 113:20 114:19 114:24 115:10	putting [2] 7:5
60:8 60:17 60:21 60:25 61:2 61:19	plug [1] 71:2 71:4	positions [5] 9:3	115:13 115:20 116:24	questions (2) 24:23
118:23	78:19 78:21 79:6 79:6 79:14 107:6	10:17 10:18 11:4	117:3 117:7 117:13 117:18 117:19 117:22	124.6
per(i) 61:7	plugged [1] 90:9	possession [3] 2:14	117:25 117:25 118:3	quick [1] 108:14
perforated [3] 54:2 54:7 76:20	point [8] 19:20 19:21	85:24 85:25	118:4 118:6 118:8 119:11 119:17 119:24	quite (1) 6:7 R (12) 13:23 13:24
perforations (1)	27:8 47:6 67:6 101:22 119:2 123:3	possibilities [2]	120:7 121:17 122:19	14:2 17:22 118:5
52:24	101:22 119:2 123:3 pointed (1) 5:20	77:2 77:3 possibility [2] 75:7	123:10 123:14 product's (21 111:10	118:9 119:4 119:16 119:25 120:9 120:23
perhaps (1) 63:3 period (2) 22:21	pointing (5) 92:12	107:24	111:24	121:10
87:3	93:5 95:9 95:10	Possibly [1] 84:13	production (20) 8:13	ramifications (2)
person (7) 62:15	102:18 poke (1) 30:11	practice (1) 83:4	33:6 33:14 33:17 33:21 34:2 34:3	74:10 74:11 Randall [1] 87:2
62:16 66:10 66:11 66:13 73:18 73:22	poked (i) 30:23	pre-cut [1] 55:16 preceding [1] 127:18	34:7 34:8 34:10	Randy [7] 1:14
personally [1] 60:21	poking [2] 30:19	preceding (i) 127:18 prefer (i) 7:5	34:23 45:11 45:13 45:24 45:25 46:10	3:13 3:15 125:2
photocopies (2) 2:20	42:12 Releases 100:16	preference [1] 7:9	46:11 46:12 46:17	126:3 126:5 127:4 rather[4] 20:8
86:2   photocopy [2]   2:21	Polar(34) 109:16	preparing (2) 51:9	74:10 products (13) 4:12	31:16 71:11 78:17
49:16	110:14 111:1 111:6	75:2	5:2 9:19 57:10	Ray (1) 3:7
photograph (s) 51:5	111:21 112:12 112:18 113:2 113:10 113:20	present (7) 2:13 5:12 38:20 38:23	59:9 59:15 59:19 62:3 63:20 63:20	Raymond [2] 2:2 2:14
51:14 52:13 58:11 69:22	114:19 115:10 115:13	93:1 99:5 116:2	62:3 63:20 63:20 80:3 81:13 123:19	razor (1) 66:12
photographed [1]	115:20 116:24 117:3 117:6 117:13 117:17	pretty [3] 41:14 60:15 90:19	profession [1] 9:20	reach [2] 99:4
52:16	117:22 117:24 118:2	preventing [1] 20:18	profile (1) 76:4	116:15
photographs [21] 2:20 2:20 5:13	118:7 118:19 119:10 119:17 120:4 120:22	previous[1] 24:11	progress(i) 111:14	read [4] 12:12 12:14 87:23 126:5
7:23 11:3 36:3	122:12 122:15 122:19	previously [1] 24:4	prohibit[1] 21:22	reading [2] 126:1
36:5 36:8 36:15 36:18 36:25 37:6	polaroid (1) 113:8	primarily (3) 15:8 68:21 96:19	16:21 111:6 111:11	127:17
37:9 37:25 38:12	polaroids [3] 124:8 124:9 124:15	primary (7) 9:3	111:12 111:19 118:20	ready (*) 25:1 32:15 33:6 33:14
38:19 58:21 77:20 85:20 113:8 115:23	polyethylene (3)	10:15 83:7 83:9	projects (1) 4:5	33:19 33:21 34:2
picture (5) 38:15	96:4 96:7 107:17	83:12 107:23 118:20 principals (2) 118:21	prototype (10) 16:3	34:10
38:16 38:13 38:15	polypropylene [2]	principals [2] 118:21	16:22 19:8 23:9	really [3] 17:1
58:17	port (43) 40:15 49:3	printed [1] 72:2	24:17 25:14 25:24 31:23 45:24 46:11	reason [4] 73:3
pictured (1) 41:6	49:6 62:20 64:7	problem (2) 31:19	prototypes (28) 14:18	89:18 126:9 126:11
5:18 7:24 8:18	64:14 64:18 64:20 65:11 65:23 67:7	111:16	15:9 15:13 16:1 17:3 17:4 17:11	reasonable (1) 86:7
8:21 12:1 12:4 . 18:16 36:22 39:1	67:16 67:24 67:25	problems (1) 31:14 procedures (3) 18:17	17:16 19:6 23:20	reasonably [1] 86:8
18:16 36:22 39:1 piece [2] 6:9 9:11	68:14 68:14 69:2 69:2 69:13 72:7	18:23 19:14	23:23 24:10 24:22	76:6 76:14
pierced (1) 70:24	72:7 72:20 72:21	proceed (1) 3:19	24:24 27:20 27:22 31:5 31:14 39:18	receiving [2] 66:6
pioneer [1] 9:9	73:4 73:11 73:13 74:2 74:3 74:24	process (2) 8:5	39:20 45:10 75:2	85:4 recess [4] 25:8
pioneering (1) 9:22	75:7 75:15 75:20	1.00.7	77:2 77:3 77:7	1,0000 [4]

pioneering (1) 9:9 73:14 73:11 73:13 process [2] 8:5 process [3] 9:22 74:3 74:3 74:24 120:7 120:

D IOMA A VOICE		CondenseIt™	`•	recite - single
RANDY ARNOLD  [54:12   85:13   124:1	relative [1] 127:9	87:17 88:25 91:1	SOC [26] 20:7 25:20	58:18 58:21 58:24
1 3 11 2 1	relay (1) 117:1	92:23 93:6 93:14	36:8 37:11 37:13	58:25 59:22 59:2 <del>5</del> 60:3 60:18 62:6
	release [5] 25:1	94:12 95:12 95:20	37:16 42:24 43:4 45:4 52:9 57:15	62:12 65:17 69:8
recognize (4) 38:25 - 89:2 89:5 100:22	69:15 69:16 69:18	98:6 98:15 101:19 104:3 107:15 124:21	58:17 58:20 72:11	79:2 85:21 85:21
recollection (11)	69:19	124:23	74:10 87:7 87:8	88:2 88:21 90:5
31:2 40:18 43:2	relinquish [1] 85:24	right-hand (2) 7:6	91:18 92:5 93:25	90:15 91:6 91:19 93:2 95:20 97:9
43:4 50:22 52:7	remained [2] 52:16	51:21	97:11 101:5 101:24 102:17 121:6 121:8	93:2 93:20 97:5 97:14 97:23 98:7
60:5 64:1 67:16	52:21	room [12] 5:6		98:17 98:21 99:6
77:5 123:2	remember [20] 7:18	5:9 5:10 5:23	seeing [18] 5:18 12:1 12:4 18:15	99:14 99:20 100:1
recommend (1) 124:22	18:17 19:6 19:8 19:14 31:20 31:21	6:19 7:10 7:24 8:18 8:22 9:17	23:4 38:18 38:22	100:7 102:2 102:6 102:14 102:16 102:20
record [48] 3:2 12:14 25:4 25:5	19:14 31:20 31:21 36:21 36:21 40:17	8:18 8:22 9:17 10:4 94:20	54:4 54:5 56:16	102:14 102:16 102:20 103:5 103:17 103:23
25:6 25:11 29:3	60:6 60:7 61:5	rooms (2) 5:15	56:18 56:22 57:7 57:10 119:13 120:22	104:7 104:21 105:13
37:18 37:19 37:20	62:9 62:11 70:24	74:16	57:10 119:13 120:22 121:21 122:6	105:20 106:18 106:22
37:23 38:4 38:6	103:25 121:22 122:6	Rothwell [2] 2:3	seem [2] 43:2 115:5	106:25 107:11 107:13
38:7 38:10 54:11 54:15 70:9 70:10	123:22	3:8	self-erect [2] 105:21	108:5 115:23 115:25
54:15 70:9 70:10 70:13 85:9 85:10	removable (1) 71:3	rough (1) 16:7	106:3	showed [4] 11:18 11:22 63:7 113:8
85:11 85:16 89:7	removed [4] 28:16 31:6 70:25 79:10	round(3) 31:3	self-erecting (2)	showing [3] 99:3
89:9 89:11 89:12	repeat [2] 12:11	53:3 55:15	106:16 106:17	103:21 103:21
89:15 89:17 96:21	97:5	rounded (11 79:5	scil (3) 63:19 63:21	shown (54) 27:16
96:23 96:24 97:2 100:11 100:12 100:13	rephrase (1) 95:5	running (1) 111:17	63:23	34:20 39:11 41:4
100:16 101:4 105:11	replaceable [1] 79:10	sale [6] 87:21 87:23	selling (4) 67:7	41:16 45:4 45:5
108:19 108:20 108:23	replaced(1) 79:11	88:1 110:22 111:24 117:5	67:16 81:23 111:1	45:10 45:23 46:10 46:18 46:19 47:13
110:9 123:25 124:4	reporter (10) 3:13	sales (3) 16:12 16:13	sense (2) 94:20	47:17 47:22 48:23
124:19 127:11	12:15 38:3 49:24	41:24	117:19	51:15 51:18 51:26
recorded [1] 127:10	80:1 85:25 86:13	sample (1) 124:11	sent (i) 71:9	52:8 52:12 52:25
rectangular [1] 84:8	108:13 109:18 127:24	Saturday (1) 37:15	separately (1)   109:20	54:18 56:12 58:1 62:3 62:18 63:18
redesign [11] 22:7 67:23 68:2 72:19	represent [1] 3:8	save [1] 77:23	105:13	62:3 62:18 63:18 69:22 70:1 71:5
74:23 75:18 75:19	request (i) 73:10	Saw [14] 36:14 36:18	scrvc [1]88:14	75:4 78:6 78:9
75:23 76:15 77:9	requested (2) 12:13	36:24 37:5 37:8	serving [1] 88:16	79:21 80:4 80:16
82:15	86:8 requests (4) 72:9	37:10 50:4 50:7	set (3) 43:15 53:15	81:6 88:2 88:21
redesigned (1) 81:3	72:11 72:14 72:17	50:10 50:10 50:19 57:12 60:21 122:14	74:16	90:5 90:14 91:5 92:16 93:13 99:5
redesigning (5) 23:16	residing (1) 15:4		setting (3) 43:11	99:19 102:2 102:14
76:17 76:18 76:25	respect [21] 6:17	Says (9) 3:18 86:22 87:1 87:3 87:4	43:14 43:18	102:20 103:4 103:17
81:5 refer to 26:14 29:19	9-19 10:3 18:4	87:16 87:17 87:20	Seventh (1) 2:9	106:18 107:10
refer (4) 26:14 29:19 93:8 93:10 100:25	18:22 19:12 24:23	101:5	Several [1] 122:10	8hows [5] 32:25
101:2	25:23 32:10 34:1 34:1 52:8 54:17	Scharf (2) 1:16	shape [7] 18:5	42:11 59:9 59:1 <b>5</b> 59:19
reference (3) 57:16	34:3 52:8 54:17 56:8 56:8 56:11	127:24	18:6 18:25 25:22	side [34] 5:22 5:23
67:21 117:24	63:18 64:14 65:23	score (4) 55:19 55:21	94:13 94:14 96:14	6:6 6:6 6:9
referenced [1] 124:14	77:17 101:11	71:1 71:6	shapes (1) 18:12	6:12 6:19 6:20
references [1] 29:3	responding (1) 73:6	scored (5) 54:2 54:7 55:23 71:2	share (1) 116:9.	6:24 7:3 7:6
referred [5] 26:20	response [1] 109:9	71:4	sharp (1) 55:20	7:11 13:10 21:21 26:9 26:12 26:13
39:18 58:2 101:9	responsible [4] 15:8	scoring (1) 52:23	sheet [1] 96:7	26:9 26:12 26:13 51:21 52:9 52:14
110:11	51:8 61:17 68:21	Scott [7] 14:23 32:10	shipped [1] 28:14	63:22 70:5 70:6
referring [6] 9:24 25:23 62:15 65:21	rest(1) 53:19	43:22 62:8 74:2	short [2] 107:1 123:23	70:23 70:25 74:17
25:23 62:15 65:21 71:5 102:24	restricted (4) 118:3	87:4 123:3	shortly [2] 122:24	79:12 91:18 91:29
refrain [3] 120:10	118:11 118:14 118:17	Scott's (3) 13:25	123:1	91:22 92:13 95:16 98:16 102:17
120:14 120:17	icenoom (i)	14:5 14:10	shoving [1] 55:11	sides (7) 70:3 70:4
refresh (1) 67:15	results [2] 23:3	sc (1) 61:7	show (100) 5:13	79:6 79:7 92:25
regard [2] 6:3	23:4	SEAL [1] 127:20	33:7 33:12 33:18	93:6 98:15
7:16	retain (2) 7:23 49:14	scaled [5] 2:14	34:9 34:20 39:3	Signed [1] 126:22
regarding [13] 5:22	1	52:16 52:21 76:22	39:7 42:16 43:7	signing [2] 126:1
7:20 7:24 67:3	retained (2) 2:24 2:25	79:3	43:12 43:14 43:25 44:11 44:24 45:15	127:17
72:17 74:2 75:6	1	seam [1] 108:5	44:11 44:24 45:15 45:18 45:21 47:18	signs (4) 21:24 56:16
77:16 116:23 116:24 117:2 122:18 122:2	.   100 ton B (-)	search[1] 18:2	50:20 50:23 51:24	118:13 118:16
regards (1) 4:25	right (15) 6:6	SCCODU (4) 14.27	52:1 52:2 52:20	similar (9) 80:17 90:19 93:15 93:16
5:1 22:12	6:19 21:6 22:5	38:5 69:15 69:18 72:20 89:10 101:2	4 52:25 53:6 53:14	
region (2) 55:15	25:2 29:25 31:4	102:18	53:15 53:19 53:21	94:12 101:13 104:13 106:19 107:2
55:16	35:24 39:13 39:15	secret (1) 117:7		similarities [1] 102:12
regular (1) 42:14	39:22 49:12 50:17	section (1) 93:4	57:11 57:12 57:22	eingleum 7:13 L
relate (1) 116:2	2 61:19 62:15 64:25 73:5 78:11 82:24	93:23 103:3	57:23 58:1 58:13	49:6 58:8 62:19
mlated to 127:1	1 (3,2 (0.11 0	1		234-2-750

related (1) 127:13 78:11 82:24 75:25 78:11 KIRBY A. KENNEDY & ASSOCIATES (612)922-1955

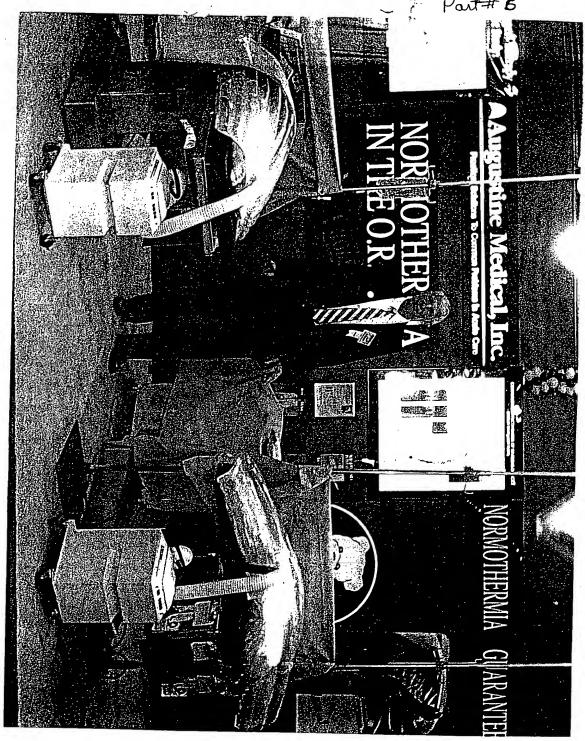
RANDY AR	NOLD			Co	ndense	elt™	_			sites	- trade
65:23 66:4	66:25		97:25	78:13				19:11	37:6 3	37:14 3	37:15
67:24 68:13	69:2		98:24	store [2]	17:12	17:14	20:16 20:19	21:21	38:12 5	50:11	50:17
72:7 74:2 75:20 76:25	74:24 77:18 -		100:2 108:18	Street (2	2}	2:4		103:15		50:19 8 91:14	85:20
78:18	17.10		112-1	2:10				3:13	threw [2]		8:9
sites (1) 121:12	1	113:24 114:13 1	114.20	stretche		12:10 15:11	Switzerland [2]	112:20	77:25	,	3.9
situation	18:10		117:8	12:21 15:18	13:3 16:5	19:13	SWOFD (2)	3:17	through	1961	10:13
113:15 115:7	10.10		120:1 120:19	23:11	10.5	17.10	127:9	3:17			27:15
situations (2)	10:18			strike (2	*11	5:21	synthetic	96:2		29:11 ;	30:7
13:6	:		87:22	19:10	29:11	31:22	system (i)	9:15			30:20
size [2] 78:19	90:21		107:6	32:24	33:4	33:11	table (5) 5:23	6:19			31:14 55:22
sketch (4)	8:18	107:7 110:8	1	47:2 61:18	53:25 71:11	54:5 73:23	89:3 106:8	106:10			56:6
8:21 15:23	15:25	sort (1) 101:10		74:15	75:13	75:23 75:18	tables (1)	5:10	57:14	60:22	76:21
19:7 24:6			14:1	77:7	78:2	78:4	taking (*)	1:15		101:7	102:11
sketched [1]	25:16	14:3		81:3	82:16	84:6	30:16 33:19	53:18	111:13	4	
sliced (1)	101:7	1	2:9	88:1			58:24 59:3	59:14	through		120:4
slid [3]   114:12   115:4	114:18	space [3]	10:22	structu		70:3	59:19 125:1	94:8	throwing thrown:	_	8:10
1	10.0	96:16 99:25		studies		112:14	tape (13) 70:13 94:9 94:9	94:8 94:15	17:18	2]	17:17
slight(1)	18:9	specific (2)   1   14:13	11:7	study (2	!]	112:18	100:5 104:8	104:9	times (3)		17:23
slightly (1)	38:17	specifically (24)	. 1	112:19			104:14 104:15	104:15		42:20	17:23
Small [2] 84:8	55:19	7:22 8:11	11:20	studyir	_	112:22	104:19 104:19		timing (		85:9
smaller (5)	78:18		18:3	subject		116:5	tcam [1] 111:11	j	tissuc (4)		95:23
81:6 81:10	90:21	31:25 43:13 4	43:17		uent (1)	67:17	tcar(1) 71:14				107:14
105:1	,		56:21	96:8	96:10	104.34	Technician (27)		title (2)		13:20
Society [1]	86:23		59:23 72:18	substat	3 <b>12 9</b> 7 (3)	104:24	3:1 3:12	3:19	today (5)		3:12
sold [35] 24:4	29:10		111:20	substar	-tielly (		25:5 25:10 37:22 38:6	37:19 38:9	27:4	78:14	106:17
29:13 29:23	29:25		121:14	87:6	87:10	88:13	54:11 54:14	70:7	124:6		l
41:16 41:18	41:23		35:25	88:14	90:17	101:25	70:12 85:10	85:15	today's	[2]	3:4
46:20 47:2	47:3	speculation [7]		substra		26:8	89:11 89:14	96:23	38:14		1
47:7 47:10 47:23 48:8	47:18 48:16	59:5 111:3	112:2	Subzer		56:20	97:1 100:12		Togethe		15:20
48:24 49:2	49:5	116:8 119:20	119:23	such		54:20	108:19 108:22 124:3 124:18	123:25	Tom [5]		71:11
56:1 56:9	58:5		4:6	75:19	81:9	91:16	techniques (1)	88:10		83:11	119:6
65:24 66:5	71:13	1	53:20	97:13	97:23	98:8	technology [4]		124:11	) <b>₩</b> [2]	124:10
79:14 79:14 82:6 83:25	80:8 110:20		73:15	98:15	98:17	104:9	10:9 10:12	10:3		76:8	1
112:6 112:8	110:20		4:1	105:14	43.33	43.7	telling (2)	73:7	took is		53:4
solve [1] 11:16			2:4	Suc (5) 62:11	43:22 62:13	62:7 62:14.	123:3		68:3	118:8	127:4
SOMEODE [4]	43:11	79:4		suffice		18:10	temporarily (1	119:17	1	79:7	106:22
58:23 59:2	114:18	SS (1) 127:2		1		10.10	ten [7] 17:8	35:8	108:1	13.1	100.2
someplace [1]	17:12	Staff [1] 118:21		Suite		04.17	35:13 40:6	41:9	torso (4)	94:1	94:4
sometime (1)	4:11	stage [1] 122:12		Summ	-	86:17	42:9 46:7			100:8	· I
sometimes (2)	30:10		49:11	500000C	ef (30) 4:15	3:24 6:1	tendency [3]	106:5	touchin		91:17
30:11	30.10		38:15	6:22	7:20	8:6	106:10 106:12		towards		38:17
somewhatm	9:14	stands (1)	120:11	9:18	12:7	12:18	term [2] 105:22	106:2	93:8	94:24	103:4
93:15 93:16			4:14	13:2	13:13	14:7	terms (1)	20:4	104:22		1
somewhere [1]	113:11	39:12 43:7	77:14	14:10	14:24	16:15	testified [2]	24:11	track [1]		
Soranno (#1)	2:8	110:25		16:17	17:4 19:18	17:5 22:11	71:12		trade (59		39:3
2:24 3:10	3:10		3:24 10:10	22:22	23:1	23:10	testify (1)	127:9	39:7	42:10	50:20 53:5
11:10 16:15	21:7		67:16	23:15	27:21	29:10	testifying (1)	127:8	50:23 53:6	52:25 53:15	53:19
24:8 24:16 28:17 28:24	26:5 29:16	74:23 122:23		29:13	30:5		testimony (3)	71:17	53:21	54:18	56:12
28:17 28:24 30:1 31:9	34:11	1 .	90:13	Sunsh	are (1)	3:3	127:10 127:12		58:1	58:25	59:9
34:16 35:9	35:16		127:2	superv	risor (1)	119:9	thank [1]	90:8	59:15	59:19	59:22
35:20 37:1	40:2	127:7	147.4	Suppo		86:16	124:6 124:17	3 -	59:25	60:3	60:18 88:2
40:7 40:11	40:19		46:15	surfac		11:1	themselves [2]	3:6	62:5 88:21	85:21 90:5	88:2 90:15
40:25 41:19	42:2 44:25	86:22 88:24	*****	76:8	,		88:12	122.24	91:6	91:19	93:2
44:6 44:19 46:22 47:24	44:25 48:4		86:20	surgeo	(כן מי	9:6	thereafter [1]	122:24	97:14	97:23	98:7
48:9 48:13	48:17	115:15		9:8	9:13		thereby [1]	127:7	98:17	98:21	99:5
49:10 49:13	49:18	1_	1:1	surgeo	(c) 8 a	23:4	thin [1] 30:12		99:14	99:19	100:1 102:6
59:4 59:10	66:20	112:9 112:9		23:5	74:15		Thirtcenth (1)	2:4	100:6	102:2 102:16	102:0
71:16 71:20	74:19	Stenotype [1]	127:11	surger	i <b>cs</b> [2]	9:4	thought [1]	6:11	103:5	103:17	
79:16 82:1	82:11	stick (1) 55:2		10:16			9:4 10:19 116:12 116:16	20:14 117:10	104:7	104:21	105:13
84:24 85:5 86:5 86:9	85:8 87:12		119:14	surger	y [i]	11:5	116:12 116:16	117.10	105:20	106:18	106:25
90:7 90:9	90:11	1	16:15	11:8	12:9		three (12)	36:5	107:11	107:13	108:5
70.7	,	0.2020 [2]		enroic	1611 12	12:25	uu cc (12)	30.3			4 4 4 4

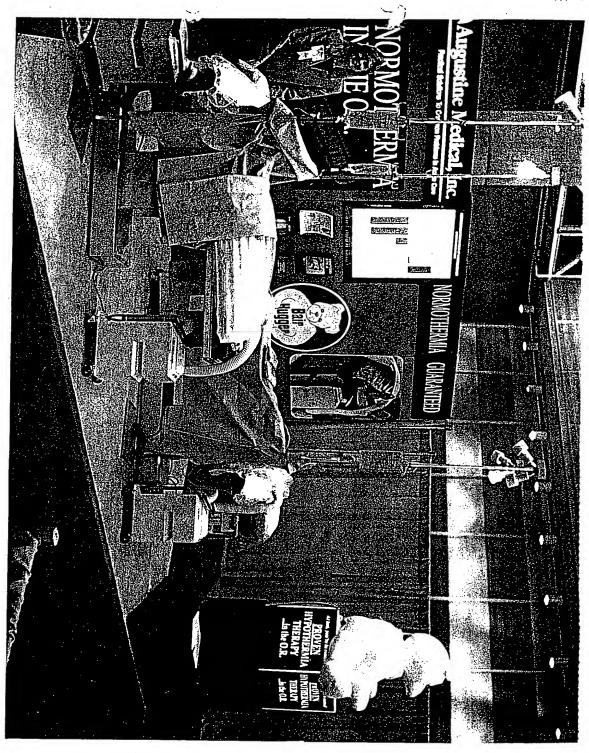
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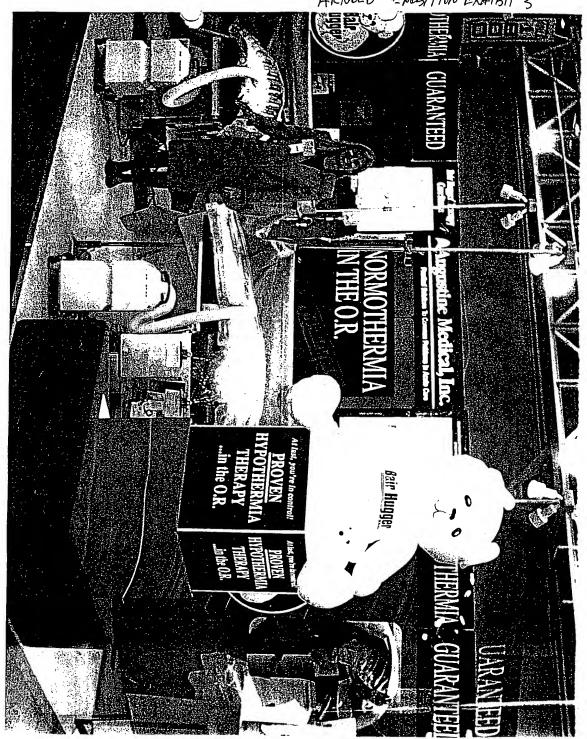
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trademark [1]		underneath [1]	106:14	80:13 81:5	80:21 81:19	80:25 87:5	127:7		127:20	1,
traditional (1)			100:6		89:5	89:20	visit (3) 5:15 123:6	123:5	WOLFF	2.9
transcribed (2)	124:22 -	understand [7]		95:21	95:24	96:4	visited (7)	56:25	Woman [2]	38:16
127:11		26:17 29:4 64:17 116:20	33:16	102:5	107:16		57:4 57:5	60:23	38:17	
transcript [5]	109:20			used (19)		22:4	60:18 60:25	61:19	words (1) worked (9)	69:25
110:2 124:21 127:14	120:0	understood [2] 55:2	24:19	26:16 65:6	64:9 65:11	64:24 66:1	visiting (2)	57:2	27:19 27:20	14:1 43:21
transport (4)	121-5	undertaken (1)	18-2	69:13	69:22	72:4	61:3		68:8 82:19	118:19
121:6 121:8	121:12	uninflated (27)		74:25	75:11	78:10	visually(1)	20:7	119:1 121:9	
transported (4)	121:17		93:13	78:13	80:20	84:9	vital (2) 21:24	56:16	workers (1)	14:17
121:21 121:24	122:2		95:6	102:1	102:5	114:3	voice[1]	3:6	writing (1)	65:18
transverse [1]	81:20		97:8 98:4	user [3] 79:12	33:17	79:10	Vosskuhler (11 44:2 113:6	143:24 115:6	written (2)	115:10
tray [7] 113:21	113:23		99:17	user's		76:11	115:16 115:19		115:12	
114:5 114:9 114:18 115:4	114:11	99:24 102:19		users (4)		54:20	115:22 116:22		Wrong [3] 116:13   116:17	87:23
trials (2) 42:7	112:11	102:24 103:2	103:3	55:1	72:3	3	122:18		X (5) 55:19	56:5
tried (1) 77:17		103:8 103:16 104:6 104:22	103:19	using (	1	7:3	VS (1) 1:8			101:22
true [4] 32:17	105:16	unit (3) 45:4	114:1	64:6	64:14	64:18	waived (1)	127:19	yea [14] 28:13	30:22
126:7 127:11		120:22		74:25 80:15	75:7	78:3	walk [1] 56:15		31:5 35:11	35:14
truth (2) 127:9	127:9	United (1)	1:1	usually	(73)	59:8	walking (1)	57:3	41:14 53:4 60:13 60:15	60:11 61:21
try (3) 34:7	97:5	112:9 112:9		101:2	141	27.0	Warm (4)	9:15	65:3 69:20	78:12
101:22		units (e) 4:12	4:15	utilized	<b>i</b> (2)	31:24	10:20 10:24 12:19 109:7	12:9	90:10 93:17	
trying(1)	9:9	45:5 45:8 45:15 47:22	45:10 113:10	42:6	• •		warmed [1]	20:9	year [16] 32:25	36:10
tube [5] 81:12	81:18		115:7	V&D [7]		121:19	warming (10)	2:23	48:3 48:7	48:15
81:20 94:25	95:2	124:9	112.7		121:20	121:22	2:23 4:12	4:15	50:8 51:3 68:7 77:15	68:5 82:10
tubes (19) 81:10 91:6	81:7 91:10	unless (2)	127:15	122:7	122:15	10.0	9:25 10:3	10:3	82:23 83:5	87:21
91:11 92:12	95:7	127:16		variatio		18:9	12:8 12:19	94:20	87:23 111:2	5
95:11 95:12	95:16	unnecessary (2)	1	various	77:16	11:4	wam [i] 117:21		years [5] 17:20	
95:21 95:21	95:22	120:10 120:18		varying		9:3	Washington (	1) 2:5	50:17 73:21	111:23
96:11 97:21 99:18 103:3	98:14 107:21	unobscured (1)		10:16	5 (-)	7.5	115:7 124:9 watch (1)	111:14	Yep [1] 86:9	
tuck (2) 20:24	21:19	up [28] 7:3	15:5 15:16	vendor	[2]	26:24	water (s)	10:5	yesterday [9] 25:20 37:9	25:16 37:10
Tuesday(1)	124:25	15:8 15:13 15:22 17:12	21:5	27:1			10:8 10:11		37:11 37:12	
turn [5] 86:21	101:23	21:13 21:22	24:25	vendor	<b>3</b> [1]	121:13	114:9		69:8 71:12	
107:5 107:8	108:8	26:22 27:15	29:11	version		69:12	week [5] 15:2	15:5	yourself [5]	5:16
turnover (1)	73:21	30:6 43:11 43:15 43:18	43:14 52:4	versus	[4]	7:13	16:24 36:20	36:24	8:19 43:5	62:4
twice (1)	42:18	43:15 43:18 53:15 74:16	81:21	7:21	47:18	48:24	weeks [3]	36:12	84:18	
Twin (2) 15:5	123:4	94:20 97:7	97:20	vertica		76:3	36:15 36:17		Zameer(1)	118:21
two [34] 7:13	7:21	102:23 123:4		video (s	µյ 3։3	2:13 3:12	weight (1)	26:7	i	
13:6 13:6	17:2	upper (97)	2:23	3:19	25:5	25:5	whereabouts   120:4   120:6	[2]	1	
22:15 22:17	24:1	10:22 11:21	11:23	25:10	25:10	37:19	1	21.20		
35:1 36:12 36:17 39:11	36:15 40:1	13:3 13:11 15:17 19:1	15:10 19:12	37:19	37:22	37:22	whole (2) 127:9	21:20	1	
60:19 63:7	63:20	19:18 22:15	23:6	38:6	38:6	38:9 54:11	wide (1) 93:19			
63:24 64:9	64:20	23:9 23:20	23:24	38:9 54:14	54:11 54:14	70:7	widerm	21:18	l	
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79:6 79:7	79:7	42:16 44:18	44:24	85:15	85:15	89:11	willing (1)	35:25		
88:9 91:13	91:14	45:21 46:9	46:10	89:11 91:17	89:14 96:23	89:14 96:23	wished [1]	79:13		
102:21 106:16		48:15 48:23	49:3	97:1	97:1	97:5	withdrawing			
type [4] 15:23	47:10	49:6 52:13 54:17 57:25	54:2 58:1	100:12	100:12		120:12	,		
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(לק) types 9:4 10:16	5:11 10:17	62:18 62:24	63:7		124:3	123:23	36:17 36:20	36:23		
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typewriting (1)		64:3 64:9 64:24 65:7	64:21 65:24	videot		1:14	52:24 53:2 54:1 54:6	53:3 55:14		
typical (1)	42:10	66:25 67:7	67:17	3:2	3:3		66:5 71:8	82:10		
typically [1]	6:5 ,	67:23 68:13	69:2	view p	1 6:18	20:10	85:3 118:2	118:9		
Uh-huzn (i)	25:21	69:2 69:13	72:7	viewed	:	115:20	119:18			
ultimately (2)		72:7 72:20	72:21	viewin	g (5)	103:8	without (1)	30:20	1	
48:24	77.70	73:4 73:10 74:2 74:3	73:13 74:18	103:14	107:25	116:24	witness [14]	3:12	1	
under (5)	29:14	74:23 75:20	75:24	117:3			3:14 3:16 24:13 24:19	24:11 108:14		. /
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ARNOLD "EARSITION EXHIBIT 3



AUGUSTINE MEDICAL 12 YEAR OLD MALE MULTIPLE TRAUMA WITH C-SPINE FRAUTURE NORMOTHERMIC AND STABLE-TO ICU BEST COPY AVAILABLE 210 155 120 90 150 180

TIME IN SURGERY



BAIR HUGGER™ CONVECTIVE WARMING THERAPY™ STARTED IN O.R.

DOCUMENT E

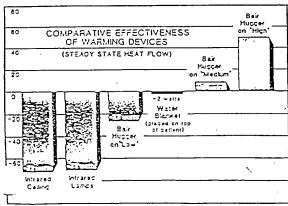
## AT LAST, YOU'RE IN CONTROL!

Augustine Medical guarantees that Bair Liugger "Convective Warming Therapy will mintain normothermia in the O.R. Far too en patients become seriously hypothermic despite the physician's best efforts. In fact, studies show that 60%-80% of all O.R. patients are hypothermic when treated with the traditional "warming" devices, which are virtually ineffective. Bair Hugger Convective Warming Therapy has actively warmed over 150,000 hypothermic PACU patients in its first year of use. It's effectiveness has been documented in several clinical studies. The proven effectiveness of Bair Hugger Therapy establishes a new standard of care. With Bair Hugger Convective Warming Therapy, hypothermia in the O.R. is a problem of the past, guaranteed!"

## Bair Hugger Convective Warming Therapy is the Only Proven Method of Active Surface Warming.

All of the available methods of surface warming were tested for effectiveness at the University of California-San Francisco. Using heat flux transducers in a controlled laboraty setting, Dr. Dan Sessler found that only air Hugger Therapy actively transfers heat to the patient. "... (Bair Hugger Therapy) provided enough heat to increase body temperature almost 3°C per hour." The other technologies did not transfer heat to the patient and in fact could not even prevent the patients from losing their endogenous heat.





"The Bair Hugger" is the first device that allows you to choose your patient's temperature and keep them there. We've had control of blood pressure and pulse for years, now we can finally control temperature."

Neil Feinglass, M.D., Jacksonville, FL

"Bair Hugge: Body Hear"

> Anelii Anelii Anelii





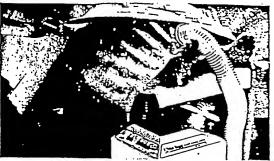




ress release, Orleans, LA, 1989 "The injured patient arrived in the O.R. cold and bradycardic. Active warming with the Bair Hugger" resulted in a rapid improvement of the temperature and stabilization of the heart rate."

-K.G. Belani, M.D., Minneapolis, MN

**AVECTIVE WARMING THERAPY** 



## Bair Hugger Warming Covers are Available in Two Styles

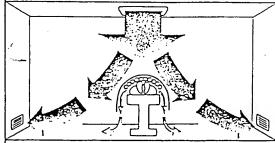
A chest/arm Cover for abdominal and lower extremity operations and a leg Cover for abdominal, thoracic and intracranial operations.

## Localized Air Flow

The combination of the Steridrape (3M, St. Paul, MN) barrier design and the overlaying surgical drape, prevents the warm exhaust air from migrating toward the surgical incision. The heated air flows from under the surgical drape toward the floor. It is then carried directly toward the room exhaust vents by the large volume of room ventilation air which is blowing directly down on the patient from the ceiling.

The warm air contributes less than 3% of the total air circulation in the O.R. and is undetectable at the surgical site. Bair Hugger air is filtered through a 0.2 micron filter before heating.

O.R. AIRFLOW IN THE OPERATING ROOM AIRFLOW: 1,300 - 26,000 CU.FT./MINUTE VELOCITY: 20 - 200 LIN.FT./MINUTE



"E HUDGOD" AIRFLOW: 35 CU.FT. /MINUTE VELOCITY: 3 LIN.FT. /MINUTE



## Bair Hugger" Convective Warming Therapy" is:

fe Convective Warming is as safe as ming up the nxxm temperature. In conast, water based warming technologies ich as water mattresses and heated umidifiers have caused numerous cases full thickness burns and trached anage."

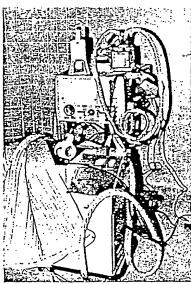
Onvenient The Bair Hugger arming System can also warm I.V. fluids nd blood! Up to one liter/hour of room imperature fluid can be warmed by simly adding two lengths of extension abing to the LV, line and placing them erween the warm air tubes of the Cover.

Ip to three liters/hour of cold blood can e warmed with a Bair Hugger "Fluid Varming Cassette which is inverted to the center air tube. Traditional fluid armers allow the fluid to cool during e six fext transit to the putient. The Buir logger System keeps the fluid warm ight up to the LV, site. Buir Hugger fluid arming is inexpensive, efficient and educes equipment needs.

Cost Effective Our simple and afe warming therapy eliminates any need or water mattresses and airway heaters. or humidification of the tracheal nucosa, we do recommend the use of an "rtificial nose" (airway Heat and Mois-Exchanger). The Bair Hugger fluid

ming capability makes blood/fluid varmers unnecessary in all but the very arge volume resuscitations.

Practical Buir Hugger Convective Warming Therapy consists of a Heating Unit and a disposable Warming Cover that directs a gentle flow of warm air across the patient's body which provides for



Bair Hugger" Therapy allows you the freedom to concentrate on the patient, not on the equipment!

safe and effective warming. The Bair Hug-ger Heating Unit uses a reliable, high efficiency blower, a sealed 850 Watt beating element, and a microprocessor based temperature controller to create a continuous flow of warm air. The patented Warming Cover is made of a layer of plastic and a layer of tissue paper/plastic luminate, bonded together into long tubular channels. When inflated, the selfsupporting Warming Cover is designed to arch over the patient's body, creating a warm "coccon". The warm air exits through microperforations in the Covers underlayer, resulting in convective warming as it surrounds the patient.

Free Trial If you are interested in effective, safe and convenient patient warming, a free trial of Buir Hugger Con-vective Warming Therapy can quickly be arranged. Just call us toll free at:

1-800-733-7775 or (612) 941-8866

\*Terms of guarantee:

Bair Hugger "Convective Warming Therapy " must begin immediately after induction of anesthesia on the "high" setting and continue throughout the case If indicated.

2. Infused blood and fluids must be warmed to body temperature.

If these two criteria are met and the patient is hypothermic at the end of the operation (core temperature 36°C). Augustine Medical will replace the Warming Cover. This guarantee is limited to the replacement of the Warming Cover.

### SPECIFICATIONS HEAT/BLOWER UNIT

Size:

Weight:
Power Requirements:
Temperature Range:
Enclosure:
Power Cable:
Filter:

Covers Arm Cover Size: Leg Cover Size: Weight:

Material:

23 high x 16 deep x 14 wice

33 ligh x lo Geep x la 32 lips 110 VAC Ambient to 110 F Max Enameled Steel 14 Feet Long High efficiency 0.2 air filter

6 ounces

Polyethylene and tissue paper latticals.



AUGUSTINE MEDICAL INC.

PRICTICAL SOUTIONS TO COMMON PROSLEMS IN ACUTE CARE-10393 West 70th Street • Eden Prairie, Minnesota 55344 Phone: 1-800-733-7775

BEST COPY AVAILABLE

(1) Youghn MH, et al: Anseth Anal 50;146-153, 1981. (2) Seasier Q, et al: One Presentation American Society of American Society of American Society (2) Seasier Q, et al: Ansethenology 36;468-111, 1972. (4) Code ML, et al: Anison Society & Environ Med 43:25-232, 1972 (5) Seasier Q, et al: Anison Society 70;4410, 1942 Comment ML, et al: Anison Society & Environ Med 43:25-232, 1972 (5) Seasier Q, et al: Anison Society 70;4410, 1942 Comment ML, et al: Anison Society & Environ ACRI Neuronal Congress, Anahom CA, Fed 1989, (8) Seasier Q, et al: Anison Society (8) Seasier C, et al: Anison Society & Environ ACRI Neuronal Congress, Anahom CA, Fed 1989, (8) Seasier Q, et al: Anison Society & Environ ACRI Neuronal Congress, Anahom CA, Fed 1989, (8) Seasier Q, et al: Anison Society & Environ ACRI Neuronal Congress, Anahom CA, Fed 1989, (8) Seasier Q, et al: Anison Society & Environ ACRI Neuronal Congress, Anahom CA, Fed 1989, (8) Seasier Q, et al: Anison Society & Environ ACRI Neuronal Congress, Anahom CA, Fed 1989, (8) Seasier Q, et al: Anison Society & Environ ACRI Neuronal Congress, Anahom CA, Fed 1989, (8) Seasier Q, et al: Anison Society & Environ ACRI Neuronal Congress, Anahom CA, Fed 1989, (8) Seasier Q, et al: Anison Society & Environ ACRI Neuronal Congress, Anahom CA, Fed 1989, (8) Seasier Q, et al: Anison Society & Environ ACRI Neuronal Congress, Anahom CA, Fed 1989, (8) Seasier Q, et al: Anison Society & Environ ACRI Neuronal Congress, Anahom CA, Fed 1989, (8) Seasier Q, et al: Anison Society & Environ ACRI Neuronal Congress, Anahom CA, Fed 1989, (8) Seasier Q, et al: Anison Society & Environ ACRI Neuronal Congress, Anahom CA, Fed 1989, (8) Seasier Q, et al: Anison Society & Environ ACRI Neuronal Congress & Environ Acri Neuronal Congress & Environ Acri Neuronal Congress & Environ Acri Neuronal Congress & Environ Acri Neuronal Congress & Environ Acri Neuronal Congress & Environ Acri Neuronal Congress & Environ Acri Neuronal Congress & Environ Acri Neuronal Congress & Environ Acri Neuronal Congress & Environ Acri N

### \*\*\* CONFIDENTIAL - FILED UNDER SEAL \*\*\*

### · UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA Fourth Division

AUGUSTINE MEDICAL, INC.,

Plaintiff,

Civil Action No. 4-94-CV-875

MALLINCKRODT GROUP, INC. and MALLINCKRODT MEDICAL, INC.,

Defendants.

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION EOR PARTIAL SUMMARY JUDGMENT OF NON-INFRINGEMENT

### BRIGGS AND MORGAN

Jeffrey J. Keyes (#66605) Jay W. Schlosser (#204353) 2400 IDS Center 80 South Eighth Street Minneapolis, Minnesota 68402 (612) 334-8400

ROTHWELL, FIGG. ERNST & KURZ, P.C.

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Raymond A. Kurz
Columbia Square
Sulta 701 East Tower
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 783-6040

ATTOKNEYS FOR DEFENDANTS
MALLINCKRODT GROUP, INC. AND
MALLINCKRODT MEDICAL, INC.
JUNE 23, 1995

DOCUEMNT F

### MMII's Thermai-olankets Do Not Infringe The '102, '520 Or '371 Patents

The three remaining asserted patents, namely, the '102, '320 and '371 Patents, are all directed to improvements to AMI's self-erecting thermal blanket. (See Lynch Decl., Exhibit D for the gencology of these three patents.) All asserted claims of the '102, '320 and '371 Patents require the "self-erecting" feature. The Summary of the Invention portions of the specifications of the '102, '320 and '371 Patents all begin with the statement that "we have improved the clinical usefulness of the self-erecting airflow cover." See Lynch Decl., Exhibits A-2, A-3 and A-4.

Importantly, each of the patent specifications contains a clear definition of what is meant by "thermal blanket":

"thermal blanket" is meant to invoke a self-erecting, inflatable structure for delivering a thermally-controlled inflating medium to the interior of the structure created when the thermal blanket is inflated.

See Lynch Decl., Exhibit A-2, column 3, lines 30-35; A-3, column 3, lines 3-7; and A-4, column 4, lines 1-4. Here, the patent specifications of the patents-in-suit perform the precise function which specifications may perform as noted by the Federal Circuit in Markman, namely, "for claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims." 52 F.3d at 979.

The '102, '320, 'and '371 Patents describe the "self-erecting" feature as follows:

When the blanket is inflated, it erects itself into a Quonset hut-like structure with a quilted upper surface.<sup>10</sup>

<sup>&</sup>lt;sup>9</sup> Although the term "self-erecting" or the similar phrase "inflatably erected" appear in nearly all of the asserted claims of these three patents, in claims such as Claim 1 of the '102 Patent, which merely refers to a "thermal blanket," AMI has admitted, as it must, that reference to "thermal blanket" is in fact a reference to the self-erecting "thermal blanket." See Lynch Decl., Exhibit G, pp. 428, lines 5-10. This is consistent with the definition of "thermal blanket" contained in the specification of each of the patents-in-suit as discussed above.

On Quonset" is defined in Webster's Third New International Dictionary as a trademark "used for a prefabricated shelter set on a foundation of bolted steel trusses and built of a semicircular arching roof of corrugated metal insulated with wood fiber." (Emphasis added.)

Lynch Decl., Exhibit A-2, column 3, lines 48-50; A-3, column 3, lines 20-22, and A-4, column 4, lines 17-19. Seemingly, there should be no controversy as to the meaning of "self-erecting" based on the clear description in the specifications of the '102, '320, and '371 Patents. Nevertheless, although AMI concedes that the term "thermal blankets" in the asserted patents means "self-erecting," AMI's position regarding this essential element is otherwise similar to the position it has taken with respect to the '188 Patent. That is, AMI advocates ignoring the clear wording of the patents as well as the prosecution histories thereof, such that "self-erecting" does not mean "self-erecting." Specifically, AMI's apparent position is that "self-erecting" means the mere expansion of the blanket ("it assumes a volume") upon being inflated with air. See, e.g., Lynch Decl., Exhibit G, p. 431, lines 23-24. According to AMI, "self-erecting" does not mean the formation of a curved or arched structure around or about the patient. See Lynch Decl., Exhibit G, p. 429, line 17 - p. 434, line 22.

AMI's position is at odds with the unequivocal language in the specification of each patent which explains that when the blanket is inflated it erects itself into a Quenset hut-like structure. Other references throughout the patents confirm the fact that prior to the litigation, AMI meant 'self-erecting" to designate a blanket formed (i.e., erected) into a curved or arched (Quenset hut-like) structure over or about a patient. See, e.g., Figures 1 and 2 of the '188 Patent (Lynch Decl., Exhibit A-1) and column 2, lines 9-13 of the '102 Patent (Lynch Decl., Exhibit A-2) which states, 'when inflated and erected over a patient, [the thermal blanket] delivers the thermally-controlled inflating medium into the interior of the structure covering the patient." Eisewhere, the '102 Patent states, "[a]s illustrated in FIG. 1, the thermal blanket of the invention is inflated, erects liself into a bathing structure and bathes a patient 26 with the thermally-controlled air used to inflate the structure." Lynch Decl., Exhibit A-2, column 4, lines 1-4.

The '320 Patent specification contains additional similar language, namely, "[w]ith these improvements, the thermal blanket, when inflated and erected over a patient . . ., " Lynch Decl.,

Exhibit A-3, column 2, lines 1-5, as does the specification of the '371 Patent ('The purpose of the thermal blanket is to efficiently administer a uniformly thermally-controlled bath of the inflating medium to a patient within the erected structure.") Lynch Decl., Exhibit A-4, column 4, lines 4-7 (emphasis added)). Additionally, the '371 Patent Abstract states, "When inflated, the thermal blanket self-erects and provides a bath of thermally-controlled medium to the interior of the erected structure..." Lynch Decl., Exhibit A-4 (emphasis added). The '320 Patent states:

An aperture array on the undersurface of the covering exhausts the thermally-controlled inflating medium from the covering into the structure created when the cover self-erects upon inflation.

Lynch Decl, Exhibit A-3, column 1, lines 58-61 (emphasis added).

Even when faced with examples such as these during his deposition, Dr. Augustine continued to insist that self-erecting does not mean forming a structure about or erected around the patient. Rather, Dr. Augustine maintained his <u>litigation</u> position that "self-erecting" only means inflating and becoming three-dimensional. See Lynch Decl., Exhibit G, p. 434, line 13 - 22. Dr. Augustine insisted that the subject matter of the asserted patents did not contemplate a blanket that erected into a structure that stood off of a person or erected about or around a person. See, e.g., Lynch Decl., Exhibit G, pp. 429, lines 4-19 and 441, lines 6-14. Instead, Dr. Augustine maintained that the Quonset hut-like structure of the patents-in-suit was formed only if the blanket was "self-erected" (i.e., inflated) over a patient, i.e., a patient is required to form the blanket into the Quonset hut. See Lynch Decl., Exhibit G, p. 437, lines 6-7. The prosecution histories of the subject patents show that this position is spurious.

For example, when arguing to the PTO that the claimed subject matter of the '102 Patent was patentably distinct from the inflatable blanket disclosed in U.S. Patent No. 4,660,388 to Greene, Jr. (the "Greene Patent," Lynch Decl., Exhibit B-4), AMI argued:

Greene failed to make two critical observations which characterize the air flow cover and its progeny and which differentiate that class of thermal blankets from the class of covers embodied in Greene. First, Greene failed to realize that the transverse plenums stiffen an inflatable pad and maintain it in an essentially planar structure which is altogether

unsuitable for "forming an enclosure" when inflated. In contrast, the airflow cover of the '188 patent and the thermal blanket described and claimed in this application do not employ transverse plenums, but, rather, communicate air between inflatable chambers by a multitude of transverse openings between the chambers. This permits the thermal blanket to assume the shape of a curved surface which curls downwardly toward its edges from its center and forms a quonset-type structure.

Lynch Decl., Exhibit C-2 (Application Serial No. 887,233) at pp. 7-8 (emphasis added).

Elsewhere, in attempting to convince the PTO that the claims of the '102 Patent were patentably distinct from the Greene Patent (as well as the patent issued to Kliesrath, U.S. Patent No. 2,110,022, Lynch Decl., Exhibit B-1), AMI argued:

In contrast [to Greene and Kliesrath], the air flow cover of the '188 patent and the thermal blanket described and claimed in this application consist entirely of:

an inflatable structure with a plurality of mutually-communicating inflatable chambers which erects into an enclosure to enclose a person; . . . .

Id. at p. 8-9 (emphasis added). AMI further stated:

Manifestly, the airflow cover of the '188 and thermal blanket of this application are significantly different than the covers of Greene and Kliesrath. They self-erect and, in doing so, eliminate the need for a non-inflating coverlet or quilt.

Id. at p. 9 (emphasis added). AMI then concluded:

Therefore, the thermal blanket disclosed and claimed in this application is different from the device disclosed by Greene because it self-erects and does not include a non-inflatable cover and means for receiving a pad, the pad alone being inflatable.

Id. (emphasis added).

During prosecution of the '320 Patent, AMI made virtually identical arguments. See '320 Patent file history (Application Serial No. 703,592), Lynch Decl., Exhibit C-3 at 13-15.

Additional similar arguments were made in the application which was the parent application to the '320 Patent and the grandparent application to the '371 and '102 Patents (Application Serial No. 227,189, Lynch Decl., Exhibit C-4). During the prosecution of the 227,189 application which eventually matured into the '102, '320 and '371 Patents, Applicants were attempting to distinguish the type of thermal blankets which were the subject of that application by

differentiating between convective thermal blankets (as in the application) and blankets which come in contact with the body (so-called "conductive" blankets). Applicants argued:

Evidently, the Examiner was under the impression that the airflow cover and the convective thermal blanket of this application operate by contacting a patient. If this were true, a much stronger relationship to the Bailey structure could be argued. However, as the applicants' representative stated, and as the enclosed photographs show, [11] the airflow cover and the convective thermal blanket, when inflated, stand off of a patient. This is vital to the blanket's operation, since contact with the patient would block passage of the inflating medium through the occluded apertures in the undersurface and would prevent the blanket from bathing the patient in an inflating medium.

Thus, while use of Bailey's conductive thermal blanket requires that it contact a person, such contact impedes correct operation of the convective thermal blanket of this application.

Lynch Decl., Exhibit C-4, pp. 3-4 (first emphasis original, second emphasis added.)

The Applicant later continued:

All of the new claims are drawn to a self-erecting inflatable thermal blanket which bathes a person in a thermally controlled inflating medium. Such a thermal blanket is one which, when inflated, erects about a person standing off a person to exhaust the inflating medium which thereby bathes the person in the medium.

### Id. at 4 (emphasis added).

There simply can be no doubt, based on a review of the prosecution histories and the patent specifications, that contrary to Dr. Augustine's position, ante litem motam, "self-erecting" does not mean merely "inflated" and reference to a "Quonset hut" structure does not mean the shape that the blanket of the asserted patents assumes only if placed on a person. As argued to the PTO by AMI, "self-erecting" means that the blanket forms a structure (like a Quonset hut) which stands off a patient. Dr. Augustine's deposition testimony must be considered to be the mere litigation posturing that it is, especially when contrasted with the pre-litigation statements made during the time that the subject patents were being prosecuted and when compared to the very language of the patents themselves.

<sup>&</sup>lt;sup>11</sup>The photographs vividly show what Applicant meent by a "self-erecting" blanket. Copies of the photographs appearing in the file history are attached to the Lynch Declaration as Exhibit C-6.

As is apparent from the photograph and drawings of the MMI blankets attached to the Virag Declaration, Composite Exhibits 1 and 2, and as described in the Virag Declaration (and as can be readily seen from a physical inspection of MMI's blankets), the accused MMI blankets do not self-erect or create a structure that arches or crects over or about the patient to stand off of the patient. To the contrary, although MMI's blankets are inflated, when inflated, they lie flat or otherwise readily conform to the shape of the person or object they cover, like a conventional blanket. Even Dr. Augustine admitted that MMI's blankets essentially take the shape of whatever they are draped over (also asserting that if placed on a patient, they "somewhat assume an arch shape"). See Lynch Decl., Exhibit G, p. 359, kine 1 to p. 360, kine 8. In fact, Dr. Augustine admitted that MMI's blankets are "archable" but are not "self-arching." Id. at p. 360, kines 2-3. Dr. Augustine also admitted that the presence of more material (described by Dr. Augustine as "redundant" material) on the underside of the blanket (as in MMI's blankets) impedes the blanket from arching. See Lynch Decl., Exhibit G, p. 315, kine 6 - p. 316, kine 7.

Significantly, even AMI's own pre-litigation Sales Training literature characterizes AMI's thermal blankets as having a "Patented arched design" and points out that MMI's blankets have "No arch design." See Lynch Decl., Exhibit F. During Dr. Augustine's deposition, he disavowed any knowledge of the AMI Sales Training literature and disagreed with the characterization contained therein, stating that the patented arch design "was written by the sales department" and "is not part of our patent." Lynch Decl., Exhibit G, p. 357, lines 14-21. Prior to being faced with the AMI Sales Training literature, Dr. Augustine testified during his deposition that the patented arch design was part of an AMI patent. Lynch Decl., Exhibit G, p. 289, lines 14-23.

It is the Court's province to interpret the subject claims as a matter of law. That interpretation leads inescapably to the conclusion that the self-erecting requirement of each of the claims of the '102, '320, and '371 Patents means the self-formation of a curved structure about, around or over the patient which stands off of the patient. Based on AMI's own

admissions, as well as the empirical viewing of MMI's blankets, it is clear that MMI's blankets do not embody this critical element of all of the asserted claims and therefore cannot infringe any of the asserted claims of the '102, '320 or '371 Patents.<sup>12</sup>

### CONCLUSION

For the foregoing reasons, it is apparent that MMI's thermal blankets do not infringe any of the asserted claims of the patents-in-suit and MMI's motion for summary judgment of noninfringement should therefore be granted.

DATED: June 23, 1995

**BRIGGS AND MORGAN** 

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<sup>&</sup>lt;sup>12</sup>Again, given the fundamental differences in construction between MMI's blankets as compared to the requirements of the asserted claims of the '102, '320 and '371 Patents, no viable claim can be made that the asserted claims of the '102, '320 and '371 Patents are infringed under the doctrine of equivalents as MMI's blankets do not perform substantially the same function, in substantially the same way, to achieve the same result, and the patents cannot be extended in contravention of the principle of prosecution history estoppel.

# UNITED STATES DISTRICT COURT DISTRICT OF MINNESOT?. FOURTH DIVISION

Augustine Medical, Inc.,

v.

CV: 4-94-875

Plaintiff,

REPORT AND RECOMMENDATION

Mallinckrodt Group Inc. and Mallinckrodt Medical, Inc.,

Defendants.

J. Randall Benham, Esq. for Plaintiff.

Jeffery J. Keyes, Esq. and Raymond A. Kurz, Esq., for Defendants.

THIS MATTER came before the undersigned United States Magistrate Judge on July 26, 1996, for a hearing on defendants' motion for partial summary judgment in which they seek a declaration of invalidity as to claims 1, 3, 4 and 8 of Plaintiff's U.S. Patent No. 5,405,371.

### i. INTRODUCTION

In a previous Report and Recommendation, dated March 18, 1996, the court summarized the general dispute between the parties and the facts related to their dispute.

The present dispute between the parties is whether claims 1,

3, 4 and 8 of AMI's '371 patent are valid. MMI argues that these
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claims are invalid because AMI displayed, sold and distributed a written description of the device covered by claims 1, 3, 4 and 8 over a year before the effective filing date of these claims, and they are therefore precluded from patent protection. See MMI's Memo at 15-16 (citing 35 U.S.C. §102(b)). AMI argues that claims 1, 3, 4 and 8 of the '371 patent were sufficiently described in the parent application such that a person skilled in the art could have made and used the device contemplated by these claims. Under the patent code therefore, AMI argues that these four claims are entitled to a filing date of July 10, 1990, which is the filing date of the parent of the application that became the '371 patent. If AMI is correct, it is of no consequence that AMI sold or displayed the device in October 1989, only nine months before the parent application was filed. More generally, AMI argues that the parent application, which is a full body blanket, contained sufficient specifications to enable a person skilled in the art to make the blankets described in the disputed claims of the '371 patent which cover only a portion of a human body such as the legs or arms.

### II. FINDINGS OF FACT

A. AMI's Patent Applications Related to the '371 Patent

The application for what became the '371 patent was filed on

January 8, 1991. It was a "continuation-in-part" application based upon a then pending application which had been filed on July 10, 1990. A copy of this application is found at Exhibit A to the Affidavit of Craig J. Lervick, and the January 8, 1991 application which resulted in the issuance of the '371 patent is found at Exhibit B. The '371 patent was issued as U.S. Patent No. 5,405,371, on April 11, 1995.

There is little evidence in the record beyond the text of the two patent applications. AMI's Memorandum in Opposition to Partial Summary Judgment summarizes the differences between the two applications. See AMI's Memo at 11 (citing Lervick Aff. at Exs. A and B).

In addition to textual differences, AMI relies upon an expert affidavit in which the expert opines that the application that resulted in the '371 patent was sufficiently disclosed in the parent application to entitle the application for the '371 patent to the

<sup>&#</sup>x27;The United States Patent and Trademark Office (\*PTO") assigns a number to each patent application it receives and to each patent it issues. Because the number of patent applications exceeds the number of patents issued by the PTO, there is no correspondence between the number assigned to a patent application and the number ultimately assigned to the patent which issues from that application. The January, 1991 CIP Application was assigned Application No. 638,748 ('748); The July 1990 parent application was assigned No. 550,757 ('757).

filing date of the parent application. <u>See</u> Daniel Campau Affidavit. MMI did not submit any expert testimony on whether the parent application sufficiently disclosed the claims of the '371 patent at issue. Rather, MMI's motion relies solely on a textual cor ipplications.

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# lone Regarding the October 1989 Display and r Body and Lower Body Blankets.

MI participated in a trade show at a meeting lety of Anesthesiologists ("the 1989 ASA; that it displayed both an upper and a lower meeting. See AMI's Memo in Opposition at 5. in 1989 it published a brochure showing an body blanket in use. See Ex. E to Jimenez does not dispute that it publicly used and dy and lower body blankets covered by the October 1989. See AMI's Memo at 5. In another these parties in federal court in St. Louis, n a motion for summary judgment, stated that in

Missour, A.f. in a motion for summary judgment, stated that in 1989 it had designed an upper body blanket with two inlets and had publicly used and displayed the blanket at the 1989 ASA Meeting.

See Ex. C to Jimenez Declaration.

### III. CONCLUSIONS OF LAW

### A. Standard of Review

The Supreme Court has held that summary judgment is to be used as a tool to isolate and dispose of claims or defenses that are either factually unsupported or are based on undisputed facts.

Celotex Corp. v. Catrett, 477 U.S. 317, 323-24 (1986); Hegg v.

United States, 817 F.2d 1328, 1331 (8th Cir. 1987). Summary judgment is proper, however, only if examination of the evidence in a light most favorable to the non-moving party reveals no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Anderson v. Liberty Lobby. Inc., 477 U.S. 242 (1986).

The test for whether there is a genuine issue of material fact is two-fold. First, the materiality of a fact is determined from the substantive law governing the claim. Only disputes over facts that might affect the outcome of the suit are relevant on summary judgment. Liberty Loboy, 477 U.S. at 252; Lomar Wholesale Grocery. Inc. v. Dieter's Gourmet Foods. Inc., 824 F.2d 582, 585 (8th Cir. 1987), cert. denied, 484 U.S. 1010 (1988). Second, any dispute of material fact must be "genuine." A dispute is genuine if the evidence is such that it could cause a reasonable jury to return a verdict for either party. Liberty Lobby, 477 U.S. at 252. It is

the non-moving party's burden to demonstrate that there is evidence to support each essential element of his claim. Celotex, 477 U.S. at 324.

Patent invalidity must be shown by clear and convincing evidence. <u>Verdegall Bros.</u>, <u>Inc. v. Union Oil Co.</u>, 814 F.2d 628, 631 (Fed.Cir. 1987). Summary judgment may be granted only when the moving party has established a right to judgment with such clarity so as to leave no room for controversy. <u>Woods v. Rhodes</u>, 994 F.2d 494, 499 (8th Cir. 1993); <u>Vacca v. Viacom Broadcasting of Mo.</u>, Inc., 875 F.2d 1337, 1339 (8th Cir. 1989).

AMI argues that summary judgment is inappropriate when the filing date of a CIP application is at issue. See AMI Memo in Opposition at 9-10. (citing see Vas-Cath. Inc., v. Mahurkar, 935 F.2d 1555, 1563 (Fed.Cir. 1991)). This assertion is wrong. While it is true that the sufficiency of the disclosure in a parent application with respect to the requirements of Section 112 must be determined on a case-by-case basis, e.g., Eiselstein v. Frank, 523 F.3d 1035, 1039-40 (Fed. Cir. 1995); Waldemar Link v. Osteonics Corp., 32 F.3d 556, 558 (Fed.Cir. 1994), and although in certain circumstances, there may be questions of fact involved in determining whether an application meets the requirements of Section 112, the ultimate conclusion is one of law and is subject

to the well-known and often quoted "genuine issue of material fact" standard. See e.g., Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

# B. AMI is Not Entitled to a Filing Date of July 10, 1990 for Claims 1, 3, 4 and 8 of the '371 Patent.

A CIP application is an application which contains subject matter from a prior application and which may contain additional matter not disclosed in the prior application. See Waldemar Link V. Osteonics Corp., 32 F.3d 556, 558 (Fed.Cir. 1994). A CIP application can be entitled to different filing dates for different claims. Id. Claims containing any matter introduced in the CIP are accorded the filing date of the CIP application. Id. However, matter disclosed in the parent application is entitled to the benefit of the filing date of the parent application. Waldemar Link v. Osteonics Corp., 32 F.3d 556, 558 (Fed.Cir. 1994). The mere fact of filing a CIP application is not determinative that the application contained new matter. Id. at 559. To qualify as a "disclosure" and thus enjoy the benefit of the prior application, the prior application must satisfy the requirements of 35 U.S.C.

§ 112. This section of the patent code provides as follows:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art...to make and use the same...

35 U.S.C. § 112, first paragraph.

In order to determine whether the disclosure of the prior application is sufficient under \$112, the fact finder must determine if one skilled in the art, reading the original specification, would immediately discern the limitation at issue in the prior application. Waldemar Link v. Osteonics Corp., 32 F.3d 556, 558 (Fed.Cir. 1994). In other words, does the "disclosure of the application relied upon reasonably convey to the artisan that the inventor had possession at that time of the later claimed subject matter?" Id. (citing Wang Labs., Inc. v. Toshiba Corp., 993 F.2d 858, 865 (Fed. Cir. 1993) (quoting Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991). Whether the original description complies with the requirement of §112 must be determined on a case-by-case basis. Eiselstein v. Frank, 52 F.3d 1035, 1039 (Fed. Cir. 1995) (citing <u>Vas-Cath</u>, 935 F.2d at 1561). Because of the fact-specificity of these cases, it is readily apparent that each case involving the question of compliance with the description requirement of \$112 must be decided on its own facts. Vas-Cath, 935 F.2d at 1562 (citing In ra Driscoll, 562 F.2d 1245, 1250 (CCPA 1977). "Thus, the precedential value of cases in this area is extremely limited." Id. (quoting In Re Driscoll, 562

F.2d at 1250).

As explained more fully below, the court concludes that the July 10, 1990 parent application does not sufficiently disclose claims 1, 3, 4, and 8 of the '371 patent to entitle these claims to the July 10, 1990 filing date. Although MMI did not submit expert testimony on the issue of whether the '757 application reasonably conveyed to a "person skilled in the art" that AMI had possession at that time of claims 1, 3, 4 and 8 of the '371 patent, the court concludes that in this case, such testimony is not required. The dispute here does not involve highly technical or scientific questions, but rather issues which are readily accessible to the court. Accordingly, the court concludes that a textual comparison of the two applications quite clearly reveals the absence of any disclosure in the July 10, 1990 parent application of the disputed claims of the '371 patent.

### 1. Claim 1

Claim 1 of the '371 patent is directed toward a thermal blanket for covering and bathing a portion of a patient's body from the pelvic area to the feet in a thermally controlled inflating medium.

See Exhibit B to Lervick Aff. at column 8 lines 33 to column 11 lines 38. In support of its position that Claim 1 was disclosed in the July 10, 1990 application, AMI states that the parent

application "clearly indicates that the thermal blanket has a flexible base sheet with a head end, foot end and two edges...and a plurality of apertures...." AMI Memo in Opp. at 13 (citing Exhibit A to Lervick Aff. at 10 and figs. 1, 2, & 4). AMI recites additional aspects of the parent application which it contends support a finding that claim 1, a lower body blanket, was sufficiently disclosed in the parent application, including: "a blanket with an overlying flexible material sheet...attached to the flexible base sheet by a plurality of discontinuous seams"; the "formation of a plurality of communicating inflatable chambers;" "substantial longitudinal disposition over the patient's body;" and a "continuous seam near the head end..." Id. at 13-14. AMI argues that the presence of these elements go toward establishing that the lower body blanket covered in claim 1 of the '371 patent was disclosed in the parent application.

In addition, AMI offers the expert affidavit of Daniel N. Campau. See AMI's Exhibit A. AMI argues that Campau's opinion is that the parent application makes numerous statements indicating that the blanket can be positioned on the patient's body at various places. Campau's entire statement regarding claim 1 is as follows:

The invention of Claim 1 provides for a thermal blanket which covers a portion of a patient's body, specifically the area extending from the pelvic region to the feet.

I find that this invention is inherent in the teaching of the '757 application. There is clear recognition that care sites must be kept visible and clean ('757 application pp. 4-5). For example, the '757 application ... describes how the blanket can be drawn up to the chin area so that the absorbent bib can be placed laterally up the neck of the patient. If the care site is above the pelvic area, it is inherent to limit the extent of the blanket to the region below the care site. Shorter blankets are contemplated in the '757 application at pg. 11. Removal of the bib and tab leaves the viewing recess defined by the continuous seam at the head end, as illustrated in Figure 6: This configuration is that required in a blanket used to cover the lower body region.

Campau Aff. at 2 (emphasis added).

First, regarding the elements of the parent application which are present in the '371 patent, the court concludes that all of these elements are merely the basic components of any inflatable warming blanket, i.e., a blanket with a flexible top sheet and a bottom sheet which are attached at the seam and which contain inflatable chambers. These are components which would exist in any size warming blanket, regardless of what portion of the body to which the blanket is directed.

Second, regarding the Campau affidavit, the court concludes that the affidavit utterly fails to explain how the parent application discloses a lower body blanket. The first sentence is merely a statement of fact; the second statement is conclusory; the third sentence is a non-sequitur and is also misleading. In the

rarent application, the recognition that "care-sites" must be kept visible and clean is made in direct reference to "care-sites" in the vicinity of the head and face. See Lervick Aff., Ex. A at 5. This does not teach or even suggest that a blanket which only covers the lower half of the body, i.e., the pelvic region to the feet, is an alternative means for keeping the face and neck area clean and visible. Nor is it necessarily "inherent" that if a "care-site" is above the pelvic region, that a blanket which only covers the lower half of the body is required. One obvious flaw in such a conclusion is the problem of how the remainder of the body is kept warm if the thermal blanket is only a lower body blanket.

In sum, the court concludes that claim 1 of the '371 patent is not disclosed in the July 10, 1990 parent application.

### 2. Claim 3

Claim 3 of the '371 patent is dependent upon claim 1; it adds the concept of including an attachment means to the head end of the blanket. See Exhibit B to Lervick Aff., column 11, lines 42-45.

AMI argues that use of an attachment in combination with the blanket described in claim 1 is sufficiently disclosed in the parent application. In support of this argument, AMI relies upon Campau's opinion, which states in full:

This claim provides for attachment means at the head end for

adhering the head end to the pelvic area to prevent the migration of air from under the blanket toward a care site. This claim is contemplated by [the] '757 application. In the '757 application at pp. 3-4 it says that "The absorbent bib also acts to some extent to seal the head end of the inflated structure." This clearly contemplates the use of other means to provide the requisite seal. Adhering the head end to the blanket to the pelvic area is a logical way to practice this teaching.

Campau Aff. at 2 (emphasis added).

The court finds no logic in these statements. It appears quite clear to the court that the statement from the parent application quoted in the Campau affidavit, "acts to some extent to seal the head end of the inflated structure" does not "clearly contemplat[e] the use of other means to provide the requisite seal." The language quoted from the parent application does not suggest that a seal is required. Rather, the quotation from the application merely indicates that the bib has the desired, but merely the incidental effect of acting as a seal "to some extent." Thus it cannot be argued that use of other means to create a seal is contemplated. Moreover, even if the parent application contemplates a required seal, nothing in the application suggests an attachment as an alternative means.

In sum, the court concludes that the July 10, 1990 application does not disclose claim 3 of the '371 patent.

### Claim 4

Similar to claim 1, claim 4 relates to an inflatable thermal blanket which covers and bathes a portion of a patient's body. See Exhibit B to Lervick Aff., column 11, lines 58-60. In claim 4, the blanket is positioned across the arms and chest of a patient's body. Id. AMI argues that the elements of claim 4 are disclosed in the following portions of the parent application: "a flexible base sheet which has a plurality of apertures;" "the overlying flexible material sheet is attached to the base sheet by a plurality of discontinuous seams;" and "the production of communicating inflatable chambers is also disclosed." AMI's Memo in Opposition at 16. AMI also argues that the parent application reveals that the blanket "could be repositioned at numerous locations over the patient's body in anticipation of the teaching of claim 4" that the "inflatable chambers are transversely disposed over the portion of the patient's body extending across the arms and chest." See AMI Memo in Opp. at 16. In support of this argument, AMI's relies on the opinion of its expert who states in full:

...It is clear that the inventors were aware that a blanket could be positioned in many ways. They were aware that various patterns of communicating chambers could be used ('757 application, p.10). They were aware that the blanket could be drawn up to the patient's chin

if needed to provide absorbency laterally up the neck of the patient. ('757 application, p.10). Any special problem created by transverse disposition is resolved by the teaching of the '757 application. If, for example, there is also a need to extend the patient's arms and provide a thermal blanket that encloses them, it is inherent in the teaching of the '757 application to provide a blanket that extends over this area. Disposing the blanket transversely is one inherent embodiment of the teaching of '757 application.

Campau Aff. at 3 (emphasis added).

contrary to the assertion of AMI's expert, the court concludes that there is simply no suggestion in the parent application as to why the pattern of inflatable tubes might be replaced by other suitable patterns of communicating, inflatable chambers. See Lervick Aff., Ex. A at 10. Similarly, neither AMI or Campau provide any explanation for how Campau leaps from the statement in the parent application that the blanket could be drawn up to the patient's chin if needed to provide lateral absorbency to the conclusion that this discloses claim 4, a blanket that covers the arms and chest. The remainder of Campau's statements regarding claim 4 and the parent application are conclusory. In sum, the court concludes that the parent application does not disclose claim 4 of the '371 patent.

### 4. Claim 8

Claim 8 is directed toward an embodiment of the invention

which is placed across the arms and chest of the patient's body. AMI recites the following elements of the parent application which it contends are incorporated into claim 8; an inflatable covering with inflatable chambers which are substantially transversely disposed over a portion of the patient's body and extending across the arms and chest of the patient; an inflating inlet; the undersurface of the inflatable cover has an array of apertures; and the existence and use of a recess for accommodating the curvature of a patient's torso. Again, AMI relies on its expert, who states:

... The first recess is similar to the head end recess taught in the '757 application. The claim recites the specific function of closing off the inflatable chambers adjacent a peripheral margin. This function follows directly from the combination of the recess and the transverse blanket orientation....

The second recess is for accommodating the patient's torso. It also closes off the inflatable chambers adjacent a second peripheral margin. The need for the second recess across the patient's torso follows from the teaching of the '757 application...which calls for a "non-inflated blanket recess...which remains smooth and flat when the blanket is inflated and erected." It follows that this recess which accommodates the patient's torso allows the covering to be adhered to the patient's chest to prevent the migration of air from underneath the blanket. The fact that this recess also closes the inflatable chambers adjacent a peripheral edge is an inherent feature of the structure.

Campau Aff. at 3 (emphasis added).

First, regarding the elements of the parent application which

AMI identifies as present in claim 8, the court observes that these are components which would exist in any size warming blanket, regardless of what portion of the body to which the blanket is directed. Second, the court observes that claim 8, like claim 4, is directed toward a blanket covering the arms and chest of a patient. Above, the court concluded that there is no basis for concluding that claim 4 is disclosed in the parent application.

Claim 8 also contains two recesses. Although the parent application contains one recess which allows viewing of the head, there is no language in the parent application which suggests a second recess, much less a second recess "for accommodating the curvature of the patient's torso" as found in claim 8. Additionally, there is nothing in the '757 application corresponding to, or suggesting an attachment at the second recess for adhering the blanket to the patient as required by claim 8. The court finds Campau's statement regarding the first recess contained in claim 6 and the disclosure of a head end recess in the parent application conclusory. Campau's statements regarding the second recess are illogical: the "non-inflated blanket recess" in the parent application occurs at the chin area and cannot be imagined to "accommodate the patient's torso" as Campau concludes. Finally, Campau fails to explain how the attachment required in claim 8 is

anticipated in the parent application.

In sum, the court concludes that claim 8 of the '371 patent is not disclosed in the parent application.

C. Claims 1, 3, 4, and 8 of the '371 Patent are Invalid because AMI Sold and Displayed these Claims More than One Year prior to the Effective Filing date of the Claims.

To prove invalidity under 35 U.S.C. Section 102(b), a person challenging a patent must show that one or more stated requirements are not met. This section of the patent code states:

A person shall be entitled to a patent unless:

(b) the invention was...described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for a patent in the United States,....

35 U.S.C. §102(b).

AMI does not dispute that in October 1989, it publicly used and described the upper body and lower body blankets covered by the disputed claims. AMI's Memo in Opposition at 5. Above the court concludes that claims 1, 3, 4, and 8 of '371 patent are not entitled to the July 1990 filing date of the alleged parent application, the '757 application. As the '748 application was filed in January 1991, over a year after claims 1, 3, 4, and 8 of the application were publicly used and described, the court concludes that AMI was not entitled to a patent for these claims and those claims are

consequently invalid. 35 U.S.C. §112(b).

### IV. RECOMMENDATION

Based upon the foregoing, and all the records, files and proceedings herein, IT IS HEREBY RECOMMENDED that:

1. Defendant's motion for summary judgment of invalidity of claims 1, 3, 4, and 8 of the '37½, patent be GRANTED.

Dated: November 8, 1996

Franklin L. Noel Chief U.S. Magistrate Judge

Under D.Minn.L.R. 72.1(c)(2) any party may object to this Report and Recommendation by filing with the Clerk of the Court, and serving all parties by  $\frac{12-(o-9)c}{c}$ , a writing which specifically identifies those portions of this Report to which objections are made and the basis of those objections. Failure to comply with this procedure shall operate as a forfeiture of the objecting party's right to seek review in the Court of Appeals. A party may respond to the objecting party's brief within ten days after service thereof. All briefs filed under this rule shall be limited to ten pages. A judge shall make a de novo determination of those portions to which objection is made.

# UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA Fourth Division

AUGUSTINE MEDICAL, INC.,

ν.

Plaintiff,

: Civil Action No. 4-94-CV-875

MALLINCKRODT GROUP INC. and MALLINCKRODT MEDICAL, INC.,

Defendants.

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY OF CLAIMS 1, 3, 4 AND 8 OF PLAINTIFF'S U.S. PATENT NO. 5,405,371

### INTRODUCTION

Defendants, Mallinckrodt Group Inc. and Mallinckrodt Medical, Inc. (collectively "MMI"), move for partial summary judgment of invalidity of claims 1, 3, 4 and 8 of Plaintiff Augustine Medical, Inc.'s ("AMI's") U.S. Patent No. 5,405,371 (the "'371 Patent"). The grounds for the motion are that there are no genuine issues of material fact in dispute as to the invalidity of these claims by virtue of AMI's admitted public use of and placing on sale a product covered by the claims more than one year prior to the effective filing date of the claims. MMI is, therefore, entitled to judgment of invalidity of such claims as a matter of law.

The general subject matter of the '371 Patent, an improved "self-erecting" type inflatable blanket, was previously discussed in detail in MMI's Partial Motion for Summary Judgment of Non-Infringement, filed June 23, 1995 ("MMI's Motion for Summary Judgment of Non-Infringement"). After consideration of the parties' positions, the Court issued a Report and Recommendation

DOCUMENT H

dated March 15, 1996 (the "Report"). (Eoth sides submitted objections to portions of the Report and such objections are subjudice.) In the Report, the Court interpreted the "self-erecting" feature required by the claims of the AMI patents-in-suit, including the '371 Patent.

Subsequent to issuance of the Report, MMI learned that the claims of the '371 Patent were invalid because AMI had, in October of 1989, more than one year prior to the effective filing date of those claims (January 8, 1991), publicly used and placed on sale (and described in a printed publication) thermal blanket products covered by the claims. MMI first became aware of this evidence of AMI's public use and sale by virtue of AMI's submission of evidence to the U.S. District Court for the Eastern District of Missouri in connection with AMI's Motion for Summary Judgment filed January 8, 1996 ("AMI's St. Louis Motion"), in Civil Action No. 4:95CV00514 MLM.

As is described below, AMI's own unequivocal admissions in its St. Louis Motion and at depositions taken in connection with that Motion establish that claims 1, 3, 4 and 8 of the '371 Patent are invalid under 35 U.S.C. § 102(b) because the subject matter of those claims was described in a printed publication and was

This case is currently pending in the United States District Court in St. Louis, Missouri, between MMI and AMI (the "St. Louis Action").

publicly used and placed on sale more than one year prior to the effective filing date of the '371 Patent.'

#### MATERIAL FACTS NOT IN DISPUTE

#### The Claimed Subject Matter

- 1. The '371 Patent (copy attached to the accompanying Declaration of Celine M. Jimenez ("Jimenez Decl.") at Exh. A) has a total of nine claims generally directed to improvements to the "self-erecting" AMI type inflatable thermal blanket. See Jimenez Decl. Exh. A, column 1, lines 43-44 ("We have improved the clinical usefulness of our self-erecting airflow cover . . ."). AMI has asserted five claims of the '371 Patent, claims 1-4 and 8, against two of MMI's warming blanket products.
- 2. Claims 1-3 of the '371 Patent, directed to a lower body style blanket for use in the operating room to cover a patient's pelvis and legs during surgery, are asserted against MMI's lower body blanket Model No. 503-0830 (the "'830 blanket"). Claims 4 and 8 of the '371 Patent, directed to an upper body style blanket for use in the operating room to cover a patient's chest and arms (outstretched) during surgery, are asserted against MMI's upper body blanket Model No. 503-0820 (the "'820 blanket").

<sup>&</sup>lt;sup>2</sup> AMI's failure to disclose to the Patent Office its prior publication, public use and placing on sale of blankets covered by claims of the '371 Patent during the prosecution of the Patent renders all claims of the Patent invalid for fraud and inequitable conduct. See 37 C.F.R. § 1.56. However, because the issue of inequitable conduct involves questions of intent and motivation which are factual in nature, in order to avoid the possibility that would attempt to raise factual disputes (although invalidity for inequitable conduct should not really be subject to serious challenge), inequitable conduct is not the subject of this Motion.

### The Lower Body Blanket Claims

3. Claim 1 of the '371 Patent recites:

In a self-erecting inflatable thermal blanket for covering and bathing a portion of a patient's body in a thermally-controlled inflating medium, the improvement comprising:

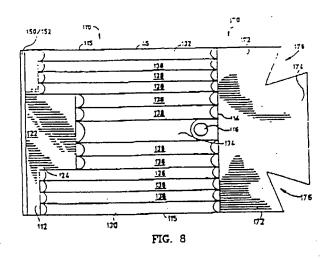
- a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;
- b) an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;
- c) said inflatable chambers in said covering for substantially longitudinal disposition over a portion of a patient's body extending substantially from the pelvic area of said patient's body to the feet of said patient's body;
- d) a continuous seam between said overlaying material sheet and said base sheet near said head end which closes ends of said inflatable chamber; and
- e) a non-inflatable section of said thermal blanket extending substantially between said continuous seam and said head end and including an end portion of said flexible sheet.

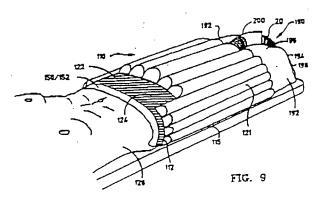
Id, at column 11, lines 14-38.

- 4. Claim 3, which is dependent on claim 1, further recites "an attachment means at said head end for adhering said head end to said pelvic area . . . " Id. at column 11, lines 42-45.
- 5. The lower body blanket of claims 1 and 3 is described and shown in the '371 Patent in Figs. 8 and 9 (Figs. 8 and 9 are

In order to avoid the possibility that AMI would attempt to raise factual disputes as to obviousness (although there should be no genuine issue of material fact in dispute), claim 2 of the '371 Patent, which recites a non-inflatable extension for covering the feet, is not the subject of this Motion. MMI does intend to show at trial that claim 2 of the '371 Patent is invalid under 35 U.S.C. § 103 for obviousness in view of prior art showing that it is conventional to cover the feet in the inflatable blanket art.

reproduced below). See siso II. at column 5, line 32 - column 9, line 44.





6. The lower body blanket of claims 1 and 3 covers the pelvic area and legs of the patient. <u>Id.</u> at column 8, lines 35-39. The blanket has a head end 112, a foot end 114, a pair a lateral edges

115, and a plurality of apertures in the base sheet through which air is exhausted into the interior of the erected structure formed by the inflated blanket. Id. at Fig 8; column 8, lines 43-54. The overlying sheet is attached to the base sheet so as to form a parallel array of elongated tubes 130, 132, 134 and 138. Id. at Figs. 8 and 9; column 9, lines 12-16. Figs. 8 and 9 show a non-inflatable section 122 extending between a continuous seam (continuous seam 40 shown generally at Fig. 2 and in column 5, lines 14-22) and the head end of the blanket. The non-inflatable section includes an end portion of the flexible sheet of the blanket 150/152. Figs. 8 and 9 show an adhesive strip 124 for adhering the head end of the blanket to the patient's pelvic area. Id. at column 8, line 58 - column 9, line 7.

## The Upper Body Blanket Claims

7. Claim 4 of the '371 Patent recites:

In a self-erecting, inflatable thermal blanket for covering and bathing a portion of a patient's body in a thermally-controlled inflating medium, the improvement comprising:

- a) a flexible base sheet having a head end. a foot end. two edges, and a plurality of apertures;
- b) an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;
- c) said inflatable chambers for substantially transverse disposition over a portion of said patient's body and extending substantially across the arms and chest of said patient's body;

- d) a continuous seam between said overlaying material sheet and said base sheet near said head end which closes ends of said inflatable chambers; and
- e) a non-inflatable section of said thermal blanket extending substantially between said continuous seam and said head end and including an end portion of said flexible sheet.

Id. at column 11, lines 46-68.

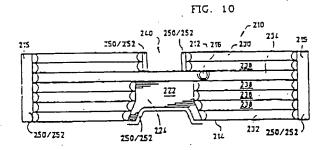
8. Claim 8 of the '371 Patent recites:

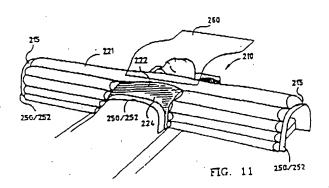
An inflatable thermal blanket for convectively controlling the temperature of a portion of a patient's body, comprising:

- a self-erecting inflatable cover with an undersurface and a plurality of substantially elongate, inflatable chambers for substantially transverse disposition over a portion of a patient's body and extending substantially across the arms and chest of said patient's body;
- an inflating inlet for admitting a thermally-controlled inflating medium into said chambers for erection of said inflatable covering;
- c) an array of apertures in said undersurface for exhausting a thermally-controlled inflating medium from said chambers through said undersurface and said patient's body;
- d) a first recess in said inflatable chambers extending across and closing off first inflatable chambers adjacent a first peripheral margin of said inflatable covering;
- e) a second recess in said inflatable chambers extending across and closing off second inflatable chambers adjacent a second peripheral margin of said inflatable covering opposite said first peripheral margin;
- f) the second recess for accommodating the curvature of said patient's torso; and
- g) attachment means at said second recess for adhering said inflatable covering to said chest and preventing migration of air from underneath said thermal blanket toward a care site.

Id. at column 12, lines 11-39.

9. The upper body blanket of claims 4 and 8 is described and shown in the '371 Patent at Figs. 10 and 11 (Figs. 10 and 11 are reproduced below). See also Id. at column 9, line 45, et seq.





10. The upper body blanket of claims 4 and 8 is a self-erecting inflatable cover with a head end 212, a foot end 214, a pair of lateral edges 215 and inflation inlet cuff 216. <u>Id.</u> at Fig. 10; column 9, lines 48-55. The overlying sheet 1s attached to the base sheet of the blanket so as to form an array of elongated tubes 230, 232, 234 and 238, disposed transversely over the arms and chest of the patient. <u>Id.</u> at column 10, lines 18-22 and 34-27; Figs. 10 and

- 11. A non-inflatable section extending between a continuous seam and the head end of the blanket and including an end portion of the flexible blanket sheet is also shown. See generally Id. at column 9, lines 48-50 (and by reference Fig. 1 and column 5, lines 14-22).
- 11. First recess 240 at the head end of the blanket and second recess at the torso end of the blanket are also shown and Figs. 10 and 11. Id. at column 9, line 66 column 10, line 2; column 10, lines 22-30. Adhesive strip 224 for attaching the blanket to the patient's chest is shown in Fig. 10. Id. at column 10, lines 3-17.

## The Effective Filing Date Of The Claims At Issue

- 12. The '371 Patent issued from a patent application, Serial No. 638,748, which was filed by AMI on January 8, 1991 (hereinafter the "'371 Application"). This application was what is known under the Rules of Patent Practice as a "continuation-in-part" of an earlier application, Serial No. 550,757 filed July 10, 1990 (hereinafter the "Parent Application"). Id. at p. 1, "Related U.S. Application Data" at part [63]; and see copy of Request for Filing Continuation-in-Part Application at Jimenez Decl., Exh. B.
- 13. A "continuation-in-part" is an application which contains subject matter, some of which was contained in an earlier "parent" application and some of which is new. The subject matter of the continuation-in-part application which was contained in the earlier parent application is entitled to the filing date of the parent application. The new material in the continuation-in-part application which was not contained in the parent application is

entitled to the filing date of the continuation-in-part application. See 35 U.S.C. § 120.

- 14. Figs. 1-7 of the '371 Patent, which show generally an AMItype self-erecting blanket, were contained in the Parent
  Application; however, Figs. 8-11 of the '371 Patent which
  specifically show the upper and lower body operating room blankets.
  covered by the claims at issue and the accompanying description to
  the Figures were new subject matter in the '371 Application and
  were not contained in the Parent Application. The subject matter
  of Figs. 8-11 and the accompanying description of them in the
  specification of the '371 Patent comprise, therefore, what is known
  as the "new matter" in the '371 Application. Id., Exh. B. This
  new matter is not entitled to the filing date of the Parent
  Application, but rather, is entitled to the date this subject mater
  was filed, January 8, 1991.
- 15. The claims at issue which are described and enabled by Figures 8-11 and their accompanying description are, therefore, entitled to the filing date of the '371 Application, namely, January 8, 1991. See 35 U.S.C. § 120.

## AMI's Motion For Summary Judgment In The St. Louis Action

16. On January 8, 1996, AMI filed a Motion for Summary Judgment in the St. Louis Action ("AMI's St. Louis Motion") and urged that the two MMI patents asserted against AMI in the St. Louis Action,

<sup>&#</sup>x27;The description added to the specification of the '371 Patent which was not contained in the Parent Application is found in the '371 Patent at column 1, line 59 through column 2, line 2; column 2, lines 21-28 and 48-51; column 3, lines 18-21 and column 8, line 32 through column 11, line 3. Id., Exh. A.

U.S. Patent Nos. 5,360,439 and 5,384,924 (collectively the "MMI Patents") were invalid. Copies of excerpts of AMI's Memorandum in support of its St. Louis Motion are attached to the Jimenez Decl. at Exh. C. Copies of the MMI Patents are attached to the Jimenez Decl. at Composite Exh. D.

designed an upper body blanket with two inlets, had described that blanket in a printed brochure distributed in October of 1989 (the "1989 Brochure"), had publicly used and displayed the blanket at an October 1989 trade show (the "1989 Trade Show"), and had placed the blanket on sale at that trade show. (These activities will be collectively referred to as "AMI's 1989 Activities"). AMI urged in its St. Louis Motion that in view of its 1989 Activities, MMI's Patents, which cover upper body blankets with more than one air inlet, were invalid under 35 U.S.C. § 102 because AMI's 1989 Activities occurred more then one year prior to the filing date of the MMI Patents. See Exh. C at 9-12.

<sup>&</sup>lt;sup>5</sup> Copy of 1989 Brochure submitted with AMI's St. Louis Motion is attached as Exh. E to the Jimenez Decl.

<sup>\*</sup> Copies of photographs submitted with AMI's St. Louis Motion which AMI asserted showed its 1989 public use and placing on sale of upper and lower body blankets are attached as Composite Exh. F to the Jimenez Decl.

AMI's St. Louis Motion did not directly concern AMI's lower body blankets; however, in the course of taking discovery in connection with the St. Louis Motion, MMI learned in more detail that AMI had also displayed, used and placed on sale a lower body blanket at the 1989 Trade Show.

<sup>\*</sup> The MMI Patents each have effective filing dates of August 3, 1992. Jimenez Decl., Exh. D.

- 18. Specifically, AMI stated in its St. Louis Motion, after describing how AMI "widely distributed" the 1989 Brochure at the 1989 Trade Show, "[c]learly, the distribution of the [1989] Dual Port Brochure at the 1989 ASA Meeting meets the printed publication requirements of 35 U.S.C. § 102(b)." Id. at 11.
- 19. AMI also stated in its St. Louis Motion that its blankers displayed and used at the 1989 Trade Show were placed "on sale" for the purposes of § 102(b). Specifically AMI stated:

The Dual Port (1989) Brochure was distributed at the 1989 ASA Meeting to encourage sales of the product. The "live" display of the Dual Fort Warming Cover served the same purpose to provoke customer interest and generate sales. This commercial activity clearly qualifies as offers for sale . . . under 35 U.S.C. § 102(b).

#### <u>Id,</u> at 12.

- asserted and admitted that its 1989 Activities constituted a description in a printed publication for the purposes of § 102(b), and constituted a public use and placing of the blankets on sale for purposes of 35 U.S.C. § 102(b). Id. at 11 12.
- 21. MMI opposed AMI's St. Louis Motion on the grounds, interalia, that the AMI blankets shown at the 1989 Trade Show did not contain a critical element of the claims of MMI's Patents, namely, the "means to selectively open said multiple inlet ports comprising a tear strip."

<sup>&</sup>quot;Claim 1 of the MMI Patents, in addition to reciting multiple air inlets, recites "means to selectively open" the inlets wherein the means comprises "a tear strip." Id., Exh. D.

- Motion, and specifically in connection with AMI's St. Louis Motion, and specifically in connection with the AMI blankets that were publicly shown, used and placed on sale at the 1989 Trade Show (and described in the 1989 Brochure). Specifically, MMI took oral depositions of the designers of those AMI blankets, Scott Augustine and Randy Arnold, both of whom attended the 1989 Trade Show. Copies of excerpts of the deposition transcripts of Scott Augustine and Randy Arnold are attached to the Jimenez Decl. at Exhs. G and H, respectively.
- 23. During their depositions, Scott Augustine and Randy Arnold confirmed under oath that AMI upper and lower body blankets were publicly used and placed on sale at the October 1989 Trade Show (and were described in the 1989 Brochure distributed at the Trade Show). Significantly, they also unequivocally confirmed that these blankets had all of the features required by claims 1, 3, 4 and 8 of the '371 Patent. Id., Exhs. G-I.
- 24. In sum, (apparently unaware that they were doing so), AMI's Scott Augustine and Randy Arnold effectively and unequivocally confirmed under oath that the '371 Patent was invalid. Id.
- Decl., Exh. I, the AMI lower body blanket shown at the 1989 Trade Show and described in the 1989 Brochure was self-erecting with a head end, foot end, two edges and a plurality of apertures (Id., Exh. E pp. 1-3 and p. 4, col, 3, Exh. F and Exh. G at p. 121, line 19 p. 122, line 7); had a plurality of discontinuous seams which formed a plurality of communicating inflatable chambers (Id.); had

inflatable chambers in a substantially longitudinal disposition over the area of the patient from the pelvis to the feet (<u>Id.</u>, Exh. E, p. 3, Exh. F, and Exh. G at p. 121, lines 19-21); had a non-inflatable section extending substantially between a continuous seam and the head end of the blanket and including an end portion of the blanket sheet (<u>Id.</u>, Exh. G at p. 120, lines 6-11 and p. 121, lines 9-14, and Exh. H at p. 103, lines 2-6, p. 108, lines 4-7); and had means for adhering the blanket at the head end to the pelvic area of the patient (<u>Id.</u>, Exh. G at p. 120, line 12 - p. 121, line 4 and Exh. H at p. 104, lines 5-20).

The AMI upper body blanket shown at the 1989 Trade Show and described in the 1989 Brochure was self-erecting (Id., Exh. E at p. 3, Exh. F, and Exh. G at p. 115, lines 22-24 and p. 116, lines 4-7); was made of a flexible base sheet having a head end, a foot end, two edges and a plurality of apertures, with the overlying sheet attached to the base sheet by a plurality of discontinuous seams which form a plurality of communicating inflatable chambers (Id., Exh. E at pp. 1-3 and 4, col. 3, and Exh. G at p. 115, lines 18-21 and p. 116, lines 8-18); had inflatable chambers for substantially transverse disposition over the patient's body extending across the arms and chest (Id., Exh. E at pp. 2 and 3, Exh. P, Exh. G at p. 116, lines 8-18 and Exh. H at p. 91, lines 4-8); had a continuous seam near the head end which closes off the end of the inflatable chambers (Id., Exh. G at p. 111, lines 19-21 and p. 113, lines 15-18); and had a non-inflatable section of the blanket extending substantially between the continuous seam and the head end of the blanket (<u>Id.</u>, Exh. G at p. 112, line 6 - p. 113, line 18 and Exh. H at p. 97, line 4 - p. 98, line 11).

- 27. The AMI upper body blanket shown at the 1989 Trade Show and described in the 1989 Brochure also had an inflating inlet (Id. Exh. E); a first recess (or cut-out) at the head end of the blanket (Id., Exh. G at p. 110, lines 17-20, p. 113, lines 15-18, and Exh. 1 attached thereto); a second recess extending across and closing off a second peripheral margin opposite the first recess to accommodate the patient's torso (Id. at p. 114, lines 3-6 and p. 114, line 18 p. 115, line 17, and Exh. H at p. 92, lines 2-4, 11-14 and p. 95, lines 4-5); and tape for attaching the blanket to the patient's chest (Id., Exh. G at p. 110, lines 17-20 and p. 114, lines 3-17, and Exh. H at p. 94, lines 6-11).
- 28. A detailed claim chart matching the claim language at issue with the features that Scott Augustine and Randy Arnold testified were present in the AMI upper and lower body blankets on sale at the 1989 Trade Show and described in the 1989 Brochure is attached to the Jimenez Decl. at Exh. I.

#### DISCUSSION

#### Applicable Law

In order for subject matter to be patentable, it must be new (novel) and non-obvious. Novelty is discussed in the Patent Statute at 35 U.S.C. § 102. Section 102 of the Patent Statute states:

A person shall be entitled to a patent unless -

(b) The invention was patented or <u>described</u> in a <u>printed</u> <u>publication</u> in this or a foreign country or <u>in public use</u>

or on sale in this country, more than one year prior to the date of the application for patent in the United States

Under 35 U.S.C. § 102(b), a patentee is barred from obtaining a patent if the subject matter of the patent was described in a printed publication or was in public use or on sale in this country more than one year prior to the filing date of the U.S. application for a patent. The portion of 35 U.S.C. § 102(b) which bars a patent if the product is "on sale" more than a year prior to the application filing date is commonly known as the "on sale bar." Events before the date one year prior to the filing of the patent can trigger the on sale bar. See McCarthy, J. Thomas, McCarthy Desk Encyclopedia of Intellectual Property, The Bureau of National Affairs, Inc. (1991) at 26.

The policy behind 35 U.S.C. § 102(b) is to give an inventor one year following the start of public disclosure or commercialization of the invention to decide whether to file an application for a patent. If no patent application is filed within that one year time frame, the right to a patent is lost. This forces the inventor to choose between seeking patent protection promptly following public disclosure (or sales activity) or taking his chances with his competitors without the benefit of patent protection. See e.g., General Electric Co., v. United States, 654 F.2d 55 (Ct. Cl. 1981).

Invalidity of a patent under 35 U.S.C. § 102 must be shown by clear and convincing evidence. <u>See Yerdegaal Bros., Inc. v. Union</u> Oil Co., 814 F.2d 628, 631 (Fed. Cir. 1987). A claim is invalid

under Section 102 if each element of the claim is found or described, expressly or equivalently, in a single prior art disclosure. Id. Whether an invention was described in a printed publication or in public use or on sale within the meaning of 35 U.S.C. § 102(b) is a question of law. See Paragon Podiatry Laboratory. Inc. v. KLM Laboratories. Inc., 984 F.2d 1182, 1186 (Fed. Cir. 1993). Summary judgment on the issue of whether a patent is invalid by virtue of the subject matter of the patent being described in a printed publication or publicly used or "on sale" more than one year prior to the filing date of the patent is proper where there are no genuing issues of material fact in dispute. Id. at 1184-85 (citing Fed. R. Civ. P. 56(c)).

# Claims 1, 3, 4 And 8 Of The '371 Patent Are Invalid By Virtue Of Their Subject Matter Being Described In A "Printed Publication," And Being Publicly Used And Placed On Sale

In October of 1989, more than one year prior to the effective filing date of the application which resulted in the '371 Patent, namely, January 8, 1991, AMI described in printed brochures, and publicly used and placed on sale, upper and lower body blankets embodying the very subject matter of the claims at issue. Accordingly, those claims are invalid under 35 U.S.C. § 102(b).

In the present case, as described above, the evidence submitted by AMI in connection with its St. Louis Motion and its own admissions at deposition clearly and convincingly show that the blankets displayed, used and on sale at the 1989 Trade Show and described in the 1989 Brochure included each and every element of claims 1, 3, 4 and 8 of the '371 Patent. In view of these

undisputed facts, no reasonable jury could fail to find that the claims at issue here are invalid by virtue of AMI's having publicly described, used and placed on sale products covered by those claims more than one year prior to the effective filing date of the claims:

#### CONCLUSION

In view of the foregoing, it is clear that MMI is entitled to judgment as a matter of law that claims 1, 3, 4 and 8 of the '371 Patent are invalid under 35 U.S.C. § 102(b).

Dated: June 28, 1996

BRIGGS AND MORGAN

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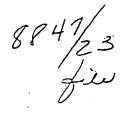
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ATTORNEYS FOR DEFENDANTS MALLINCKRODT GROUP, INC. AND MALLINCKRODT MEDICAL, INC.

758659.1

## STATE OF MINNESOTA COUNTY OF HENNEPIN



.T OF SERVICE

METRO LEGAL SERVICES, INC.

Daniel J. Pribek, being duly sworn, on oath says: that on the 17th day of July, 1996, at 5:05 p.m. (s)he served the attached Memorandum of Augustine Medical, Inc. in Opposition to Motion for Partial Summary Judgment, Affidavit of Daniel N. Campau, and Affidavit of Jay Lervick upon Jay W. Schlosser, Esq. therein named, personally at 2400 IDS Tower, Minneapolis, County of Hennepin, State of Minnesota, by handing to and leaving with Sam Lovejoy, receptionist, an expressly authorized agent for service for said Jay W. Schlosser, Esq., a true and correct copy thereof.

Subscribed and Sworn to before me this 17th day of July 1896.

Notary Public

Charge \$

CARRIE ESHETE

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TO THIS TO THE TO

#### UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA FOURTH DIVISION

Augustine Medical, Inc.,

Civ. No. 4-94-CV-875

Plaintiff.

vs.

Mallinekrodt Group, Inc. and Mallinekrodt Medical, Inc., MEMORANDUM
OF AUGUSTINE MEDICAL, INC.
IN OPPOSITION TO MOTION FOR
PARTIAL SUMMARY JUDGMENT

Defendants.

### INTRODUCTION

"Mallinckrodt") rely on unsupported legal conclusions, wrongly identified as "undisputed facts," as grounds for partial summary judgment. Specifically, Mallinckrodt asks the Court to assume that the patent claims at issue have an effective filing date of January 8, 1991. Mallinckrodt is incorrect because the subject matter of the claims at issue! was described in a parent application which has a filing date of July 10, 1990, six months earlier than the filing date asserted by Mallinckrodt. At the very least, whether the claims were described in the parent application is a disputed issue of fact which precludes the entry of partial summary judgment. Indeed, whether

DOCUMENT I

Mallinckrodt seeks summary judgment only as to claims 1, 3, 4 and 8 of AMI's patent no. 5,405,371. AMI has also asserted claim 2 of the '371 Patent against Mallinckrodt, which is not a subject of Mallinckrodt's Motion (see Mallinckrodt's Memorandum of Law at 4 n. 3) as well as United States patents '188, '320 and '102 which also are not the subject of Mallinckrodt's Motion.

subject matter is described in a parent application is an inherently factual question that is not suitable for resolution by summary judgment.

The disputed claims are entitled to a filing date of no later than July 10, 1990. As a result, the activities of Augustine Medical, Inc. ("AMI") in October 1989 upon which Mallinckrodt bases its argument cannot be cited as prior art. The one year startutory bar startite cited by Mallinckrodt in its motion -- 35 U.S.C. § 102(b) -- simply does not apply. Mallinckrodt's Motion for Summary Judgment should be denied.

#### **EACIS**

#### A. The '371 Patent.

United States patent no. 4,504,371 (the "'371 Patent") issued on April 11, 1995 from U.S. patent application no. 638,748 (the "'748 application"). The '748 application was a continuation-in-part application ("CIP application") which included information from three earlier filed related applications, all of which were abandoned in favor of continuations. All of the related applications are listed on the first page of the '371 Patent. See Ex. A to the Declaration of Celine M. Simenez ("Jimenez Decl."). The specific details of each application are outlined below.

First, on October 5, 1987, AMI Medical, Inc. filed U.S. patent application no. 104,682 titled "THERMAL BLANKET" (the "great-grandparent application"). This application was abandoned on December 5, 1988.

Next, on October 2, 1988, AMI filed U.S. parent application no. 227,189 titled "THERMAL BLANKET" (the "grandparent application"). This grandparent application was a CIP of the great-grandparent application and included much of the material that is contained in the '371 Patent. The grandparent application was abandoned on July 1, 1991.

On July 10, 1990, a turd CTP application was filed as U.S. patent application no. 550,757 (the "parent application"). Again, this application was titled "THERMAL BLANKET" and again contained much of the same description which exists in the '371 Patent. A copy of the parent application is attached as Exhibit A to the Affidavit of Craig J. Lervick ("Lervick Affidavit").<sup>1</sup>

Finally, on January 8, 1991, the '748 application was filed as a CIP of the parent application. The '748 application ultimately issued as the '371 Patent.' In graphical format, the progression of related applications leading up to the '371 Patent looks like:

For convenient reference, the application numbers are set out below in chart form.

Application	Application Serial No.	Filing Date	Description
Great-grandparent	104,682	10/05/87	Original patent application
Grandparent	227,189	10/02/88	CIP application based on 104,682
Parent	550,757	07/10/90	CIP application based on 227,189
'748 Application	638,748	01/08/91	CIP application based on 550,757

The parent application was continued as U.S. application no. 887,233 on May 19, 1992 (which issued as U.S. patent no. 5,300,102).

Great-grandparent 104,682 Filed 10/05/87 Original patent application Grandparent 227,189 Filed 10/02/88 CIP application based on 104,682 V Parent 550,757 Filed 07/10/90 CIP application based on 227,189 '748 Application 638,748 Filed 01/08/91 CIP application based on 550,757

Each application related to the '371 Patent was filed as a CIP<sup>4</sup> application and claimed the benefit of its predecessor applications under the patent laws. See 35 U.S.C. § 120. Additionally, application was filed by the same inventors and was filed during the pendency of its predecessor application.

A CIP application repeats a portion of a prior application and may also add clarification, elaboration or new matter not disclosed in the earlier one. As Mallinckrodt concedes, the subject matter of the CIP application which was included in the prior application is entitled to a filing date of the prior application while new subject matter, if any, provided only in the CIP application is given the filing date of the CIP application. See Waldemar Link v. Osteonics Corp., 32 F.3d 556, 558 (Fed. Cir. 1994); see also Mallinckrodt's Memorandum of Law ¶13 at 9.

#### B. AMI's 1984 activities.

As stated in Mallinckrodt's Memorandum, in 1989 AMI published a brochure showing an upper body and a lower body blanket in use. Additionally, AMI participated in the 1989 Annual Meeting of the American Society of Anesthesiologists (1989 ASA meeting) in New Orleans, Louisiana on October 14-18, 1989. AMI displayed both an upper body and a lower body blanket at its booth (these activities collectively "AMI's 1989 activities").

AMI does not dispute that it publicly used and described upper body and lower body blankets covered by the disputed claims in October 1989. These activities are irrelevant, however, to the validity of the claims at issue. The activities did not occur more than one year prior to the July 10, 1990 filing of the parent application for the '371 Patent'.

#### ARGUMENT

#### I. STANDARD - SUMMARY JUDGMENT.

Summary judgment is appropriate only when the moving party demonstrates that there is no genuine issue as to any material fact and that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). "Summary judgment will not lie if the dispute about a material fact is genuine, that is, if the evidence is such that a reasonable jury could return a verdict for the moving party." Anderson v. Liberty Lobby, 477 U.S. 242, 248, 106 S.Ct. 2505, 2510, 91 L.Ed.2d 202, 208 (1986).

Mallinckrodt incorrectly and misleadingly focuses its argument exclusively on the fact that AMI's disclosure of the invention in October 1989 is undisputed. See Mallinckrodt's Memorandum of Law at 16-18. Mallinckrodt fails to prove an absence of genuine dispute as to whether the subject matter of the claims was described in the July 10, 1990 parent application, a dispute which precludes summary judgment. In fact, Mallinckrodt does not address this issue at all, thus failing to meet its burden to show an absence of genuine disputes of material fact.

The role of the court is not to weigh the evidence, but instead to determine whether a genuine factual dispute exists. Id. at 249, AgriStor Leasing v. Farrow, 826 F.2d 752, 734 (8th Cir. 1987); Tower Ins. Co., Inc. v. Judge, 840 F. Supp. 679, 684 (D. Minn. 1993). In making this determination, "the evidence must be viewed in a light most favorable to the party opposing summary judgment". Paragon Podiatry Laboratory v. KLM Laboratories, 984 F.2d 1182, 1185 (Fed. Cir. 1993) (citting, United States v. Diebold, Inc., 369 U.S. 654, 655, 82 S.Ct. 993, 993, 8 L.Ed.2d 176 (1962)); see also AgriStor, 826 F.2d at 734; Tower Ins., 840 F. Supp. at 684; Minnesota Pet-Breeders, Inc. v. Schell & Kampeter, Inc., 843 F. Supp. 506, 510 (D. Minn. 1992).

As Mallinckrodt concedes, patent invalidity must be shown by clear and convincing evidence. Mallinckrodt's Memorandum of Law at 16, citing Verdegeal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631 (Fed. Cir. 1987). Summary judgment may be granted only when the moving party has established the right to judgment with such clarity so as to leave no room for controversy. Woods v. Rhodes, 994 F.2d 494, 499 (8th Cir. 1993); Vacca v. Viacom Broadcasting of Mo., Inc., 875 F.2d 1337, 1339 (8th Cir. 1989); see also Paragon at 1185 ("summary judgment is authorized when it is quite clear what the truth is").

#### II. DETERMINATIONS OF VALIDITY UNDER 35 U.S.C. § 102.

Mallinckrodt has asserted that claims 1, 3, 4 and 8 of the '371 Patent are invalid under 35 U.S.C. § 102(b).

U.S. patents are accorded a presumption of validity. 35 U.S.C. § 282. To prove invalidity under 35 U.S.C. § 102(b), Mallinckrodt must show that one or more stated requirements were not met. This Code section states in relevant part that:

A person shall be entitled to a patent unless -

(b) The invention was . . . described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for a patent in the United States, . . . .

#### U.S.C. § 102(b) (emphasis added).

As is apparent from the specific language of the Code, the application of this section requires a specific determination of the "date of the application for a patent." When dealing with CIP applications, this determination can be complex.

#### III. CONTINUATION-IN-PART APPLICATIONS.

A CIP application contains subject matter from a prior application and may contain additional matter not disclosed in the prior application. "A CIP application can be entitled to different... [filing dates] for different claims. Claims containing any matter introduced in the CIP are accorded the filing date of the CIP application. However, matter disclosed in the parent application is entitled to the benefit of the filing date of the parent application." Waldemar Link v. Osteonics Corp., 32 F.3d 556, 558 (Fed. Cir. 1994).

#### A. Determination of CIP Application's Filing Date.

The plain fact that a CIP application was filed is not determinative that the application contained new marter. See, Waldemar, 32 F.3d at 559 (Mere filing of a CIP is not a concession that the parent application contained an insufficient disclosure.)

A CIP application can be filed for numerous reasons. "Such an application may for example contribute a 'mere embellishment or technical improvement of a feature disclosed in the original application, which does not contribute to its novelty, utility or non-obviousness' or may merely elaborate on the disclosures of earlier applications." Hughes Aircraft Co. v. United States, 640 F.2d 1193, 1198 (Ct. Cl. 1980) (quoting Acme Highway Products Corp. v. D. S. Brown Company, 431 F.2d 1094, 1080 (6th Cir. 1970), cert. denled, 401 U.S. 956, 91 S.Ct. 977, 28 L.Ed.2d 239 (1971)), and see Azoplate Corp. v. Silverlith. Inc., 367 F.Supp. 711, 732 (D.Del. 1973), aff d 506 F.2d 1050 (3d Cir. 1974), cert. denled, 421 U.S. 914, 95 S.Ct. 1572, 43 L.Ed.2d 780 (1975).

The assessment of validity under 35 U.S.C. § 102(b) of a patent issued from a CIP application, therefore, requires a determination of each claim's filing date. The principles for determining the filing date of claims contained in a CIP application are outlined in 35 U.S.C. § 120. This section states:

An application for parent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the parenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

35 U.S.C. § 120.

#### B. Disclosure Under 35 U.S.C. § 112.

To qualify as a "disclosure" – and thereby enjoy the benefit of the prior filing date – the prior application must satisfy the requirements of 35 U.S.C. § 112 first paragraph. This paragraph states as follows:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art... to make and use the same....

#### 35 U.S.C. § 112, ¶ 1.

In summary, the first paragraph of 35 U.S.C. § 112 requires an adequate written description of the invention – a description which would enable one skilled in the art to make and use the invention. See Vas-Cath. Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

The requirement for a "written description of the invention" is separate and distinct, however, from the enablement requirement.

#### 1. Written description requirement.

The test for sufficiency of the written description in a parent application "is whether the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." Wang Laboratories v. Toshiba Corp., 995 F.2d 858, 865 (Fed. Cir. 1993) (quoting, Vas-Cath\_Inc. at 1563).

The issue of whether a parent specification adequately describes the subject matter claimed is a question of fact. In re Alton. 76 F.3d 1168, 1171-72 (Fed. Cir. 1996) (citing VasaCath. Inc. at 1563). Specifically, "compliance with the written description aspect... is a question of fact" Waldemar Link at 558 (citing Utter v. Hiraga. 845 F.2d 993, 998 (Fed. Cir. 1988)).

#### 2. Enablement requirement.

Similarly, satisfaction of the enablement requirement also involves questions of fact.

See, In re Varck, 947 F.2d 488, 495 (Fed. Cir. 1991). ("Enablement . . . is a question of law which we independently review, although based upon underlying factual findings which we review for clear error.")

C. <u>Summary Judgment is Inappropriate When The Filing Date of a CIP</u>

Application Is At Issue.

Both the written description requirement and the enablement requirement involve questions of fact. Consequently, when a genuine dispute of fact arises regarding the filing date

of claims in a CIP application, summary judgment is inappropriate. See, Vas-Cath. Inc. at 1567 (summary judgment award reversed because issues regarding the written description requirement gave rise to genuine issues of material fact). See also H. B. Fuller Co. v. National Sterch & Chemical Corp., 595 F. Supp. 622, 624 (D. Del. 1984) (the issue of whether a parent application discloses the invention claimed in a CIP application is "highly technical and subject to competing interpretation... In other words, there are key factual issues yet to be resolved after a full consideration of the evidence and summary judgment must thus be denied."): Max Daetwyler Corp. v. Input Graphics. Inc., 608 F. Supp. 1549 (E.D. Penn. 1985) (motion in limine denied because it was impossible to conclude as a matter of law that a later application was not entitled to the benefit of the filing dates of earlier applications).

#### IV. THE CLAIMS AT ISSUE ARE NOT BARRED.

The activities giving rise to Mallinckrodt's Motion for Partial Summary Judgment occurred on October 14, 1989. The "critical date" for purposes of 35 U.S.C. § 102(b) is, therefore, October 14, 1990. For an inventor to be entitled to a patent covering subject matter

In this case, the issue already is before the Patent Office. On June 5, 1996 AMI filed an application for reissue of the '371 Patent. See Affidavit of Robert M. Rauker attached to the July 2, 1996 letter from Jake M. Holdreith to the Court. This application requested reissue without limitation of the term "self-erecting". In the reissue application, AMI revealed the October 1989 disclosure, placing all relevant information before the Patent Examiner. As allowed by Patent Office rules (37 CFR § 1.11(b)), any other parties, including Mallinckrodt, may submit all information deemed relevant to the patentability of the reissue application. AMI previously requested that the Court cominue its decision on Mallinckrodt's partial summary judgment motion pending the decision of the Patent Examiner. See July 2, 1996 letter of Make M. Holdreith requesting stay of the present motion. The Court denied AMI's request by an order dated June 12, 1996. AMI respectfully submits that allowing the Patent Office to consider this issue would enhance judicial economy because the PTO's decision could (1) moot the Motion if the patent is invalidated based on the issues raised by Mallinckrodt in the present Motion, or in the alternative (2) provide the Court with guidance as to whether the disputed claims were adequately described in the parent application.

disclosed at the 1989 ASA meeting, an application for patent must have been filed prior to October 14, 1990 (the "critical date").

The parent application and all previous related applications were filed prior to the critical date. As the '371 Patent is entitled to enjoy the benefit of a filing date no later than that of the parent application, the claims at issue were also filed before the critical date.

#### A. COMPARISON OF '748 APPLICATION AND PARENT APPLICATION.

A comparison of the '748 application and its parent reveals that much of the text contained in the '748 application is also disclosed in the parent application. More importantly, the invention of the claims at issue was sufficiently disclosed in the parent application to inform an "artisan that the inventor had possession at that time of the later claimed subject matter." See Wang at 865. Therefore, the claims at issue have a filing date no later than the filing date of the parent application — July 10, 1990.

A detailed comparison of these two applications reveals that text was added to and/or changed in the '748 application (and consequently, the '371 patent) at only the following places: 9

The abstract was rewritten;

Figures 8 through 11 were added;

As the parent application and all preceding applications were filed prior to the critical date, this Memorandum will discuss only relation back to the parent application. A more thorough review of the '371 Parent history will reveal that certain subject matter contained in the application is entitled to the benefit of the filing date of the great-grandparent application (October 5, 1987). AMI only need show that the claims at issue are entitled to the benefit of the filing date of the parent application to defeat Mallinckrodt's Motion.

For the convenience of the Court, Exhibit B of the Lervick Affidavit includes a copy of the '371 Patent in which all text added to a specification in the '748 application has been highlighted. All of the text which is not highlighted relates back to the July 10, 1990 filing date of the parent application.

Text was added at column 1, line 59 through column 2, line 2;

At column 2, line 4, "method therefor" was added;

Text was added at column 2, lines 21 through 27, lines 44 through 46, and lines 49 through 51;

At column 3, line 8, "patient's head and face" was replaced with -care site-;

At line 13 -legs and/or- was added;

Text was added at column 3, lines 18 through 21 and lines 49 through 60; and

Text was added at column 8, line 32 through column 11, line 3; and at column 11, lines 5 through 9.

All other text in the '748 application was included in the parent application.

#### B. THE PARENT APPLICATION PROVIDES AN ADEQUATE DISCLOSURE.

The disclosure in the parent application reasonably conveys to one skilled in the art that the inventor had possession at the time of the claimed subject matter. In opposition to Mallinckrodt's Motion, AMI has filed herewith the Affidavit of Daniel N. Campau. As set forth in Mr. Campau's Affidavit, the parent application reasonably conveys to one skilled in the art that the inventors had possession of the subject of the disputed claims. See Affidavit of Daniel M. Campau ("Campau Aff.") (indicating that all the claims at issue are sufficiently disclosed in the parent application). Consequently the claims at issue are entitled to the filing date of the parent application. See Yas-Cath. Inc., at 1553 (restating the test for the written description requirement).

A. Claim I is sufficiently disclosed in the parent application.

Claim 1 is directed toward a thermal blanket for covering and bathing a portion of a patient's body from the pelvic area to the feer in a thermally controlled inflating medium. Claim 1 specifically states:

 In a self-erecting inflatable thermal blanker for covering and bathing a portion of a patient's body in a thermallycontrolled inflating medium, the improvement comprising:

a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;

an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;

said inflatable chambers in said covering for substantially longitudinal disposition over a portion of a patient's body extending substantially from the pelvic area of said patient's body to the feet of said patient's body;'

a continuous seam between said overlaying material sheet and said base sheet near said head end which closes ends of said inflatable chamber, and

a non-inflatable section of said thermal blanket extending substantially between said continuous seam and said head end and including an end portion of said flexible sheet.

Exhibit B to the Lervick Affidavit at column 11, lines 14-38.

The disclosure in the parent application clearly indicates that the thermal blanket has a flexible base sheet with a head end, foot end and two edges (see Exhibit A to the Lervick Affidavit (parent application) at p. 10 and at figs. 1, 2 & 4) and a plurality of apertures (see Id. at p. 7). The disclosure describes the blanket to have an overlying flexible material sheet (see Id. at p. 11) which are attached to the flexible base sheet by a plurality of discontinuous seams (see Exhibit A to the Lervick Affidavit at p. 9). The parent disclosure indicates the formation of a plurality of communicating inflatable chambers (see Id. at p. 9). The parent application discloses substantial longitudinal disposition over the patient's body (see Id., Figures 1 through 7). A

continuous seam near the head end also is disclosed in the parent application (see [d. at p. 9). Lastly, the specification of the parent application discloses a non-inflatable section substantially between the continuous seam and said head end (see [d. at p. 8).

In addition to the above-cited references, the parent application makes numerous statements indicating that the blanket can be positioned on the patient's body at various places. As indicated by expert Campau, the parent application recognizes that care sites must be visible and clean. Campau Affidavit at 2. A care site, of course, can exist at numerous places on a patient's body. The parent application also indicates that the viewing recess permits observation of the patient's head, face, neck and chest from any location. Exhibit A to Lervick Affidavit (parent application) at 8. This suggests that the blanket can be appropriately positioned to accommodate whatever viewing requirements are necessary. For example, the disclosure indicates that the blanket can be drawn up to the patient's chin. Id. at p. 10. As confirmed by expert Campau, this reveals that the blanket can be positioned variously on the patient's body. One variation of such positioning could cover the patient from the pelvic area to the feet. Campau Affidavit at p. 2.

The subject matter claimed in claim 1 was sufficiently disclosed in the parent application.

Claim 1, therefore, is clearly emitted to the filling date of the parent application.

#### B. Claim 3 is sufficiently described in the parent application.

Claim 3 of the '371 Patent is dependent upon claim 1. This claim further adds the concept of including an attachment means to the head end of the blanket. 10 Use of an attachment

<sup>10</sup> Claim 3 of the '371 Patent states as follows:

means in combination with the blanket described in claim 1 is also sufficiently disclosed in the parent application.

As recognized by expert Campau, "the absorbent bib...acts...to seal the head end of the inflated structure." Exhibit A to the Lervick Affidavit (parent application) at pp. 3-4. This information "clearly contemplates the use of other means to provide the requisite seal." Campau Affidavit at 2. Alternatively stated, the disclosure in the parent application sufficiently discloses the invention of claim 3.

#### C. Claim 4 is sufficiently described in the parent application.

Similar to claim 1, claim 4 relates to an inflatable thermal blanket while covering and bathing a portion of a patient's body. In claim 4, however, the blanket is positioned across the arms and chest of a patient's body. More specifically, claim 1 states:

- 4. In a self-erecting inflatable thermal blanket for covering and bathing a portion of a patient's body in a thermally-controlled inflating medium, the improvement comprising:
- a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;
- an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;
- said inflatable chambers for substantially transverse disposition over a portion of said patient's body and extending substantially across the arms and chest of said patient's body;
- a continuous seam between said overlaying material sheet and said base sheet near said head end which closes ends of said inflatable chambers; and

Exhibit B to Lervick Affidavit, column 11, lines 42-45.

<sup>3.</sup> The improvement of claim 1 further including an attachment means at said head end for adhering said head end to said pelvic area and preventing migration of air from under said thermal blanket toward a care site.

a non-inflamble section of said thermal blanket extending substantially between said continuous seam and said head end and including an end portion of said flexible sheet.

Exhibit B to the Lervick Affidavit column 11, lines 46-68.

The elements of claim 4 are disclosed sufficiently in the parent application reasonably convey to an artisan that the inventor had possession at the time of filing of the subject matter claimed. The Disclosures of the parent application includes the following:

Claim 4 first requires a flexible base sheet. This flexible base sheet appears in the Parent application at p.10 (see Exhibit A to the Lervick Affidavit (parent application) at p. 10). The flexible base sheet is said to have a plurality of apertures therein. The apertures are disclosed in the parent application. Exhibit A to the Lervick Affidavit (parent application) at p. 7.

Next, the second paragraph of claim 4 requires an overlying flexible material sheet. This overlying flexible material sheet is disclosed at p. 11. See Exhibit A to the Lervick Affidavit (parent application) p. 11. Claim 4 also requires that the overlying flexible material sheet be attached to the base sheet by a plurality of discontinuous seams. The disclosure of discontinuous seams is found in the parent application. Id. at p. 9. Claim 4 states that attachment of a base sheet by a plurality of discontinuous seams forms said overlaying material sheet into a plurality of communicating inflatable chambers. The production of communicating inflatable chambers is also disclosed. Id.

Claim 4 then states that the inflatable chambers are transversely disposed over a portion of the patient's body extending across the arms and chest. As indicated by expert Campau, the applicants revealed that the blanket could be repositioned at numerous locations over the patient's body. Campau Affidavit at pp. 2-3. Furthermore, claim 4 requires that the inflatable chambers be transversely disposed over a patient's body. Figures 1 and 2 of the parent

application clearly show the array of chambers situated transverse to a patient's body. See Exhibit A to the Lervick Affidavit (parent application), Figures 1 and 2. The claim does not require that a single chamber run transverse to the patient's body. Consequently, the claim is not limited to a specific alignment of the inflatable chambers. Furthermore, the parent application clearly indicates that structures other than tubes shown in Figures 1 through 6 could be used. See, Campau Affidavit at p. 3, and Exhibit A to the Lervick Affidavit (parent application) at p. 8. The tubes, therefore, can run different directions than those specifically revealed.

The combination of these numerous concepts clearly indicates that the inventor at the time of filing the parent application had in his possession the claimed subject matter.

Next, claim 4 requires a continuous seam near the head end. Such a continuous seam is clearly shown in the parent application at p. 9. See Exhibit A to the Lervick Affidavit (parent application) at p. 9).

Lastly, claim 4 in the final paragraph requires a non-inflatable section extending between the continuous seam and the head end. Once again, this description was clearly shown in the parent application. See Exhibit A to the Lervick Affidavit (parent application) at p. 8.

The parent application sufficiently discloses the subject matter claimed in claim 4. Consequently, this claim is also entitled to the benefit of a filing date no later than that of the parent application.

#### D. Claim 8 is entitled to the filing date of the parent application.

Claim 8 is directed toward an embodiment of the invention which is placed across the arms and chest of the patient's body. Specifically, claim 8 states:

8. An inflatable thermal blanket for convectively controlling the temperature of a portion of a patient's body, comprising:

a self-erecting inflatable cover with an undersurface and a plurality of substantially elongate, inflatable chambers for substantially transverse disposition over a portion of a patient's body and extending substantially across the arms and chest of said patient's body;

an inflating inlet for admitting a thermally-controlled inflating medium into said chambers for erection of said inflatable covering;

an array of apertures in said undersurface for exhausting a thermally-controlled inflating medium from said chambers through said undersurface to a space between said undersurface and said patient's body;

- a first recess in said inflatable chambers extending across and closing off first inflatable chambers adjacent a first peripheral margin of said inflatable covering;
- a second recess in said inflatable chambers extending across and closing off second inflatable chambers adjacent a second peripheral margin of said inflatable covering opposite said first peripheral margin;

the second recess for accommodating the curvature of said patient's torso; and

attachment means at said second recess for adhering said inflatable covering to said chest and preventing migration of air from underneath said thermal blanket toward a care site.

Exhibit B to the Lervick Affidavit, column 12, lines 11-39.

The invention claimed in claim 8 is disclosed in the parent application. This conclusion is affirmed by expert Campau. See Campau Affidavit at p. 1. Claim 8 is therefore also entitled to the benefit of the filing date of that application.

The first paragraph of claim 8 recites an inflatable cover with a plurality of elongate inflatable chambers. An inflatable covering with inflatable chambers is clearly disclosed in the parent application. See Exhibit A to the Lervick Affidavir (parent application) at p. 11. This paragraph also requires the chambers be substantially transversely disposed over a portion of the patient's body and extending across the arms and chest of the patient. As detailed regarding

claim 4, the applicant, in the parent application, clearly disclosed this possibility. All elements of this paragraph are disclosed in the parent application.

The next paragraph of claim 8 requires an inflating inlet. The inflation inlet or inflation inlet cuff is shown which accommodates the inflation of the blanket. See Exhibit A to the Lervick Affidavit (parent application) at p. 7.

The next paragraph of claim 8 requires that the undersurface of the inflatable cover has an array of apertures. These apertures are disclosed in the parent application at page 7. Exhibit A to the Lervick Affidavit (parent application) at 7.

In the next two paragraphs, a first recess and a second recess, extending across and closing off inflatable chambers are required. Page 8 of the parent application (Exhibit A to the Lervick Affidavit) clearly shows the existence and use of a recess. Furthermore, Figures 1, 2 and 5 all show a recess in the blanker's configuration. See also Campau Affidavit at p. 3. Consequently, the use of a recess or recesses were clearly contemplated by the applicants at the time of the parent application.

The next paragraph states that the second recess is for accommodating the curvature of a patient's torso. As previously stated, the use of a recess was clearly contemplated by the inventors at the time of filing the parent application. See Campau Affidavit at p. 3. Additionally, the placement of the blanket at numerous places on the patient's body is disclosed. Therefore, this concept was sufficiently disclosed in the parent application.

The description in the parent application sufficiently discloses to an artisan that the invention claimed in claim 8 was within the inventor's possession. Claim 8 is entitled to the benefit of a filing date no later than July 10, 1990.

#### CONCLUSION

Mallinckrodt has failed to establish by clear and convincing evidence that the parent application does not reasonably convey to the artisan that AMI had possession of the subject matter of claims 1, 3, 4 and 8 of AMI's patent 5,405,371. Mallinckrodt, in fact, has not even addressed the issue of whether the elements of the claims at issue were adequately disclosed in the July 10, 1990 application. As noted by the Federal Circuit, a determination of whether subject matter provides a clear description to an artisan is inherently unsuitable for summary judgment. The question of whether — in the eyes of a person skilled in the art — the disclosures in the parent, grandparent or great-grandparent applications were sufficient should be left to the jury.

Summary judgment should be denied.

Date: July 17, 1996

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ATTORNEYS FOR PLAINTIFF AUGUSTINE MEDICAL, INC.

#### UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA FOURTH DIVISION

AUGUSTINE MEDICAL, INC.,

Civil Action No. 4-94-CV-875

Plaintiff,

DEFENDANTS' REPLY TO MEMORANDUM OF AUGUSTINE

MALLINCKRODT GROUP INC. and

MEDICAL, INC. IN OPPOSITION TO DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT

MALLINCKRODT MEDICAL, INC.,

Defendants.

#### INTRODUCTION

Plaintiff Augustine Medical, Inc.'s ("AMI's") Memorandum in Opposition to Defendants' Mallinckrodt Group Inc.'s and Mallinckrodt Medical, Inc.'s (collectively "MMI's") Motion for Partial Summary Judgment of Invalidity of U.S. Patent No. 5,405,371 (the "371 Patent"), does not dispute the fact that the subject matter of claims 1, 3, 4 and 8 of that Patent was described in a printed publication, and was publicly used and placed on sale by virtue of AMI's 1989 Activities. Rather, AMI only makes the legal argument that the subject matter of the claims at issue was sufficiently described and enabled by an earlier parent application (Serial No. 550,757, the "Parent Application"), such that the claims are entitled to the filing date of that earlier application.2 AMI takes this position despite the

DOCUMENT J

<sup>&#</sup>x27;The meanings of the defined terms used in MMI's Motion for Partial Summary Judgment of Invalidity of Claims 1, 3, 4 and 8 of U.S. Patent No. 5,405,371 ("MMI's Motion") are incorporated herein by reference. AMI's Memorandum in Opposition to Motion for Partial Summary Judgment is hereinafter referred to as "AMI's Opposition."

The filing date of the Parent Application is July, 1990. Accordingly, if the subject claims were given this filing date, the October 1989 Activities would, by approximately three months, not be a statutory, § 102(b) bar to the patentability of the claims.

fact that when it filed its continuation-in-part application which resulted in the '371 Patent (the "CIP Application"), it rewrote the Abstract in the CIP Application to change the focus of the application to blankets which only cover a portion of a body, such as the legs or arms, and added more than three columns of written description and four figures specifically describing and showing the upper and lower body blankets of the claims at issue. The modifications of and additions to the text and Figures in the CIP Application belie AMI's littlgation-induced position that the subject claims were sufficiently described and enabled by the Parent Application. AMI's arguments fall under their own weight and are nothing more than a desperate attempt to salvage patent claims which are clearly invalid in view of AMI's own admissions regarding its 1989 Activities.

The weakness of AMI's position is perhaps best exemplified by the very Affidavit which AMI proffers to support its position, namely, the Affidavit of Daniel N. Campau ("Campau Affidavit"). As discussed more fully below, in order to prevail in its opposition to MMI's Motion, AMI must show that a reasonable fact finder could conclude that the Parent Application would "convey with reasonable clarity" to those of skill in the art that AMI was "in possession of the invention of claims 1, 3, 4 and 8 and that one reading the specification of the Parent Application "would immediately discern" the claim limitations at issue. Far from meeting these standards, the Campau Affidavit shows that there was not even a hint of the lower and upper body blankets of claims 1, 3, 4 and 8 in the Parent Application, much less any description which would "convey with reasonable clarity" or enable one to "immediately discern" the claimed subject matter.

As is clear from the Campau Affidavit itself, and as is described in more detail below, there is no genuine dispute that the subject matter of the claims at issue was not sufficiently

described and enabled in the Parent Application and no reasonable jury could find that the '371 Patent is not invalid.

#### **ARGUMENT**

The standard for summary judgment provides that the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact. See Paragon Podiatry Laboratory v. KLM Laboratories, 984 F.2d 1182 (Fed. Cir. 1993) (citing Anderson v. Liberty Lobby, Inc., 477 U.S. 242 (1986)) (emphasis original). The proper inquiry, therefore, is whether the evidence presents a sufficient disagreement to require submission to a jury or whether it so one-sided that one party must prevail as a matter of law. Id. In this case, it is clear from the '371 Patent and the Parent Application, that the claims at issue are not entitled to the filing date of the Parent Application because there is no written description of the subject matter of those claims in the Parent Application so as to enable a person skilled in the art to make and use the invention, as required under 35 U.S.C. § 112.

For a later filed application to be entitled to the benefit of the date of a previously filed application, the previously filed application must contain a written description of the invention which complies with the requirement of the first paragraph of 35 U.S.C. § 112. In order to meet the written description requirement of § 112, the description in the patent application must clearly allow person(s) of ordinary skill in the art to recognize that the applicant invented what is claimed. That is, the applicant must "convey with reasonable clarity" to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. See In re Alson, 76 F.3d 1168, 1172 (Fed. Cir. 1996). It must

be determined whether one reading the specification of the earlier application "would immediately discern" the claim limitations at issue. See Waldemar Link v. Osteonics Corp., 32 F.3d 556, 558 (Fed. Cir. 1994).

The issue of whether an application satisfies the requirements of 35 U.S.C. § 112, first paragraph, is a question of law based on underlying issues of fact (the issue of whether a patent specification meets the written description requirement under § 112 involves questions of fact). Id. Accordingly, as with all motions for summary judgment, where there is no genuine dispute as to issues of material fact, summary judgment is appropriate. The present case is just such a case.

There Is Nothing In The Parent Application Which In Any Way Indicates That AMI Was "In Possession Of" The Later Claimed Subject Matter

Although the Campau Affidavit conclusorily states that the parent application "reasonably conveys" the subject matter of the claims at issue, that statement is not supported by any logical interpretation of the Parent Application and '371 Patent specification. The Affidavit does not (because it cannot) reference any portion of the Parent Application that specifically describes the subject matter of the claims. Rather, the Campau Affidavit almost exclusively relies on vague allegations that the subject matter of the claims

<sup>&</sup>lt;sup>3</sup>AMI's bare assertion in its Opposition at 9, that "summary judgment is inappropriate when the filing date of a CIP application is at issue" is wrong. The sufficiency of the disclosure in a parent application with respect to the requirements of § 112 must be determined on a case-by-case basis. Eiselstein v. Frank, 52 F.3d 1035, 1039-40 (Fed. Cir. 1995) (where the court found claims directed to a range of nickel content in an alloy of "from about 45% to about 55% of the alloy" to be sufficiently described under § 112 by the specification which described a "nickel in a weight proportion of 45% to 55% of the alloy," but did not find claims reciting a balance "with nickel constituting about 50 to about 60% of the alloy" to be sufficiently described by the specification). Though in certain circumstances, there may be questions of fact involved in determining whether an application meets the requirements of § 112, the ultimate conclusion is one of law (similar to an infringement analysis) and is subject to the well-known and often quoted "genuine issue of material fact" standard. See Anderson, 477 U.S. at 247-248.

is "inherent" in the teachings of the Parent Application. However, the loose and expansive use of the term "inherent" in the Campau Affidavit and in AMI's Opposition is a misapplication of the legal standard under § 112 and highlights the deficiencies in AMI's position.

Moreover, even if principles of inherency were appropriate here (although, in actuality they are not), the doctrine of inherency is necessarily limited by the description requirement of § 112 and the party relying on inherency bears the burden of proving that the disclosure of the parent application would necessarily lead one skilled in the art to the claimed subject matter. See Wagner v. Barger, 463 F.2d 1377 (C.C.P.A. 1972). The fact that later disclosed material might have been surmised from the earlier application is insufficient. See Fox Indus., Inc. v. Smucrural Preservation Systems, Inc., 6 U.S.P.Q.2d 1577, 1590 (D. Md. 1988); 4 Chisum Patents, § 13.04[4] at 13-32. AMI's Opposition and the Campau Affidavit do not on their face meet the standard required by § 112 and, therefore, AMI's Opposition raises no genuine issue of material fact. The specifications of the Parent Application and the '371 Patent are so starkly contrary to the conclusory statements in the Campau Affidavit that the Affidavit should be given no weight.

<sup>&#</sup>x27;Principals of inherency in the context of sufficiency of disclosure are generally applied where a claim element and patent specification describe a property of a structure, albeit in arguably varying terms (e.g., the claim recites an elastomer of a "low crystallization type" and the specification describes an elastomer "with high resistance to sunlight and pavement erosion," see Acme Highway Prod. Co. v. D. S. Brown Co., 431 F.2d 1074 (6th Cir. 1970)). The question then becomes whether one of skill in the art would immediately recognize that the specification necessarily described the claimed property of the structure. Such principles are not applicable in this case where AMI attempts to read into the Parent Application whole devices and parts of devices which simply are not there. See also Mendenhall v. Cedarapids, Inc., 28 U.S.P.Q.2d 1081, 1088-89 (Fed. Cir. 1993).

There is absolutely no written description in the Parent Application of the following subject matter of claim 1 of the '371 Patent.'

a "self-erecting inflatable thermal blanket for covering and bathing a portion of a patient's body in a thermally-controlled inflating medium;"

inflatable chambers in the covering "for substantially longitudinal disposition over a portion of a patient's body extending substantially from the pelvic area of said patient's body to the feet of said patient's body; and

"a non-inflatable section . . . extending substantially between" the continuous seam and the head end of the blanket.

Rather, the lower body blanket of claim 1 is described only in the new material added to the specification of the '371 Patent when the CIP Application was filed on January 8, 1991. For example, under the Summary of the Invention, the following language was added on January 8, 1991:

Finally, we have observed that our self-erecting air flow cover may be advantageously adapted to thermally control specific partial portions of the patient such as the legs and lower body or the arms and upper body leaving other areas of the patient available for care and treatment.

Column 1, lines 59-64. The lower body blanket is more fully described in the '371 Patent at column 8, line 32 - column 9, line 44, and in Figs. 8 and 9. All of this written description, including Figs. 8 and 9, represents material that was added in the CIP Application filed on January 8, 1991. Prior to that date, there is not a single word in the Parent Application of a blanket designed to cover only a portion of a patient's body, much less the legs or lower body as recited by claim 1.

<sup>&</sup>lt;sup>5</sup>For sake of brevity, MMI only discusses the elements of the subject claims of the '371 Patent which are glaringly absent from the Parent Application.

AMI does not argue, because it cannot, that a written description of the subject matter of claim 1 is expressly contained in the specification of the '371 Patent. Rather, AMI asserts in its Opposition at 14 that the Parent Application makes statements "indicating" that the blanket "could be" positioned on the patient's body at various places," and "suggests" that the blanket "can be" appropriately positioned to accommodate whatever viewing requirements are necessary. AMI's assertions, even if correct, do not meet the legal test under the written description and enablement requirements of § 112. See, e.g., Wagner. Even under principles of inherency, the party asserting that later filed claims are entitled to the filing date of an earlier parent application bears the burden of proving that the disclosure of the parent application would necessarily, not "might," lead one skilled in the art to the claimed subject matter, and AMI makes no such assertion. See Wagner.

Further, AMI's assertions are not supported by the specification of the Parent Application and are patently unreasonable. For example, AMI asserts in its Opposition at 14 that, "The Parent Application makes numerous statements indicating that the blanket can be positioned on the patient's body at various places." However, AMI's Opposition provides no support for this statement. This is because there is no support to be found in the Parent Application.

AMI also asserts in its Opposition at 14 that the Parent Application recognizes that "care sites" must be kept visible and clean (citing Campau Affidavit at 2), and then urges that "A care site, of course, can exist at numerous places on a patient's body." However, the only reference to "care site" in the portions of the Parent Application cited at p. 2 of the Campau Affidavit (i.e., pp. 4-5 of the Parent Application), specifically indicates only a "care site in the vicinity of the patient's head and face." Parent Application at 5. Even more importantly, it is extraordinary, to say the least, that AMI can assert in good faith that the

Parent Application's reference to "means for maintaining the cleanliness of the care site in the vicinity of the patient's head and face" in any way supports, much less, allows one to "immediately discern" the claimed subject matter directed to a self-erecting inflatable blanket covering a "portion" of a patient's body and having chambers for "substantially longitudinal disposition over a portion of a patient's body extending substantially from the pelvic area of said patient's body to the feet of said patient's body."

Equally extraordinary (yet indicative of the weakness of AMI's Opposition) is AMI's reliance on the statement in the Parent Application that "the blanket can be drawn up to the chin area so that the absorbent bib can be placed laterally up the neck of the patient," to support AMI's assertion that the lower body blanket of claim 1 is "inherently" described in the specification of the '371 Patent. AMI Opposition at 14; Campau Affidavit at 2. Query, how does the statement that "the absorbent bib can be drawn up to the chin of a patient" allow one to "immediately discern" the claimed invention of a lower body blanket? AMI's position is patently nonsensical.

As can be seen from the Summary of the Invention portion of the '371 Patent which was added when the CIP Application was filed in January of 1991, AMI described its "invention" as a "self-erecting air-flow cover that may be advantageously adapted to thermally control specific partial portions of the patient such as the legs and lower body or the arms and upper body leaving other areas of the patient available for care and treatment." Column 1, lines 59-64 (emphasis added). AMI's reliance on an assertion that "care sites must be visible and clean," or that the "absorbent bib can be drawn up to the chin area" suggest nothing about the lower body airflow cover of claim 1 which is described in the Summary of the Invention as "advantageously adapted to thermally control specific partial portions of the patient such as the legs and lower body."

In sum, no reasonable jury could find that the Parent' Application's reference to "means for maintaining the cleanliness of the care site in the vicinity of the patient's head and face" and an absorbent bib with an indent cut into its outside edge which permits the blanket to be drawn up to the chin so that the absorbent bib can be placed laterally up the neck of the patient would permit one to "immediately discern" the limitations of claim 1, namely, a blanket for covering "a portion" of a patient's body "extending substantially from the pelvic area of the patient's body to the feet . . ."

Moreover, although the Campau Affidavit states "if the care site is above the pelvic area it is inherent to limit the extent of the blanket to the region below the care site," there is absolutely nothing in the Parent Application which even suggests limiting the blanket to a region below a care site. The assertion in the Campau Affidavit that "Shorter blankets are contemplated in the '757 application at page 11" is in error as there is no mention of a shorter blanket in the Parent Application. No reasonable jury could find that there is any language in the Parent Application (much less language which "conveys with reasonable clarity") that AMI was in possession of an "invention" of a lower body blanket as of July 1990 when it filed its Parent Application.

# Claim 3, Also Directed To A Lower Body Blanket, Is Not Described Or Enabled By The Parent Application

Claim 3 of the '371 Patent depends from claim 1 (and therefore contains all limitations of claim 1) and in addition recites "an attachment means at said head end (of the blanket) for adhering said head end to said pelvic area and preventing migration of air from under said thermal blanket to the care site." The only mention of any attachment means

<sup>&</sup>lt;sup>6</sup>Since Claim 1 is unsupported by the Parent Application, Claim 3 is also necessarily unsupported by the parent Application. However, as set forth below, the additional subject matter of Claim 3 is also not described or suggested in the Parent Application.

or structure for adhering the blanket to any portion of the budy is in the portion of the specification of the '371 Patent which was added when the CIP Application was filed on January 8, 1991 and shows an adhesive strip (e.g., column 8, line 58 - column 9, line 7). Contrary to AMI's implication in its Opposition at 15, there is no mention whatsoever in the Parent Application of the absorbent bib disclosed in that Application having an adhesive strip or any other means for physically attaching the blanket to the patient.

Here, AMI relies on the statements in the Campau Affidavit at 2 that, "The absorbent bib also acts to some extent to seal the head end of the inflated structure. This clearly contemplates the use of other means to provide the requisite seal." This statement, however, sheds no light on the limitation of claim 3 which recites an attachment means for adhering the blanket to the pelvic area of the patient. First, the Campau Affidavit does not even state that the absorbent bib disclosed in the Parent Application has structure, such as the adhesive strip disclosed in the CIP Application, for attaching the blanket to the body of the patient. Further, the language of the Parent Application quoted in the Campau Affidavit refers to sealing the head end of the inflated structure (not "sealing" the blanket to the body). Moreover, there is no limitation in claim 3 reciting a "requisite seal."

In sum, the unsupported and weak statements in the Campau Affidavit do not meet the legal test under § 112 and show the lack of any genuine disputed issue of fact. No reasonable jury could find that one of skill in the art would "immediately discern" the "attachment means" at the head end of the blanket for "adhering said head end to said pelvic area and preventing migration of from under said thermal blanket towards a care site," from the quoted language in the Parent Application regarding the absorbent bib.

AMI's assertions that the Parent Application contains a written description of an upper body blanket for "covering and bathing a portion of a patient's body" and having "chambers for substantially transverse deposition over a portion of said patient's body and extending substantially across the arms and chest of said patient's body" as required by claim 4 of the '371 Patent, are frivolous. There is no hint in the Parent Application of a blanket that covers only a portion of a patient's body (here, only the arms and chest), as explained above, and there is no hint in the Parent Application of a blanket with chambers transversely disposed over and extending across the arms and chest of the patient. Rather, the written description supporting the subject matter of claim 4, namely, an upper body blanket, is described in the '371 Patent at column 9, line 45 - column 11, line 12; the upper body blanket including the transversely disposed chambers extending across the arms and chest of the patient is shown in Figs. 10 and 11 - all of which description was added when the CIP Application was filed on January 8, 1991.

The statement in the Campau Affidavit at 2-3 that AMI was "aware that the blanker could be positioned in many ways," is notable only in that it is not supported by any citation to the Parent Application (because neither that statement nor any statement to that effect is contained in the Parent Application). Also, one cannot discern what the statements in the Campau Affidavit at 3 regarding "various patterns of communicating chambers" or by virtue of an indent in the absorbent bib "the blanket could be drawn up to the patient's chin if needed to provide absorbency laterally up the neck of the patient," have to do with a blanket for bathing a "portion" of a patient's body having "inflatable chambers for substantially transverse disposition over" and "extending substantially across the arms and chest" of the

patient, as recited in claim 4. The chambers disclosed in the CIP Application for the upper body blanket are in an elongated "tube" pattern (i.e., the issue of various patterns does not apply); however, they run perpendicular (i.e., transverse) to the trunk of the patient's body and extend only across the arms and chest of the patient. This subject matter is clearly not described in the Parent Application.

AMI also urges that Figs. 1 and 2 of the Parent Application show an "array of chambers situated transverse to a patient's body," AMI's Memorandum at 17. There is no statement to that effect in the Campau Affidavit, and in any event, AMI does not assert (because it cannot) that any of the Figures in the Parent Application describe or show chambers "for substantially transverse disposition" "extending substantially across the arms and chest of said patient's body" as required by claim 4. In sum, AMI has come forward with absolutely no evidence that it was in possession of an invention relating to an upper body blanket when it filed the Parent Application and no reasonable jury could find that one reading the specification of the Parent Application "would immediately discern" the subject matter of claim 4.

Claim 8, Also Directed To An Upper Body Blanket, Is Not Described Or Enabled By The Parent Application

There is also no hint in the Parent Application of the following subject mater of claim 8 of the '371 Patent.

"An inflatable thermal blanket for convectively controlling the temperature of a portion of a patient's body;"

"a self-erecting inflatable cover with an undersurface and a plurality of substantially elongate, inflatable chambers for substantially transverse disposition over a portion of a patient's body and extending substantially across the arms and chest of said patient's body;"

"a first recess in said inflatable chambers extending across and closing off first inflatable chambers adjacent a first peripheral margin . . .," and "a second

recess in said intracole chambers extending across and closing off second inflatable chambers adjacent a second peripheral margin... opposite said first peripheral margin," the second recess "for accommodating the curvature of the patient's torso;" and

"attachment means at said second recess for adhering said inflatable covering to said chest and preventing migration of air from underneath said thermal blanket toward a care site."

As explained above, there is nothing in the Parent Application describing or referring to a blanket which covers only the patient's arms and chest with chambers disposed transversely over and extending across the arms and chest.

As to the other elements of claim 8, AMI urges in its Opposition at 19 that the use of a recess at the patient's chin as shown in Figs. 1, 2 and 5 of the Parent Application constitutes a written description of the first and second recesses recited in claim 8. It is quite clear, however, from a review of the Parent Application that the one recess shown in Figs. 1, 2 and 5 is for enabling viewing of the head, Parent Application at 10, (not the torso). AMI can point to no language in the Parent Application which even suggests a second recess opposite a first recess, much less a second recess "for accommodating the curvature of the patient's torso" as recited in claim 8. There is also no mention or suggestion in the Parent Application, as explained above, of an attachment means (such as an adhesive strip) at the second recess for adhering the blanket to the patient as required by claim 8.

In support of AMI's assertions with respect to the "attachment means" of claim 8, the Campau Affidavit states:

The need for a second recess across the patient's torso follows from the teaching of the '757 application at p. 8 which calls for "a non-inflated blanket recess... which remains smooth and flat when the blanket is inflated and erected." It follows that this recess which accommodates the patient's torso allows the covering to be adhered to the patient's chest.

The statement is nonsensical on its face. The "non-inflated blanket recess" referenced in the Parent Application is at the chin area and does not "accommodate the patient's torso." The statement also ignores the requirement of <u>structure for attaching</u> the blanket (i.e., "attachment means") to the patient at the second recess.

#### CONCLUSION

AMI's Opposition is unsupported and insupportable. AMI is obviously grasping at straws to attempt to avoid invalidation of the '371 Patent claims at issue. The fact of the matter, of course, is that AMI invalidated its '371 Patent when it publicly described, used and placed on sale, its lower and upper body blankets, more than one year before fling for a patent on those blankets. One questions how AMI can seriously contend that the Parent Application in any way provides a written description and enables the subject matter recited in claims 1, 3, 4 and 8 of the '371 Patent, much less that the Parent Application "conveys with reasonable clarity" or allows one of ordinary skill in the art to "immediately discern" the subject matter of the claims. It is, therefore, respectfully urged that summary judgment of invalidity of the '371 Patent is appropriate and entry of partial summary judgment as to that patent is respectfully requested.

Respectfully submitted,

OF COUNSEL:

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(612) 334-8400

By

ATTORNEYS FOR DEFENDANTS

#### AFFIDAVIT OF SERVICE

STATE OF MINNESOTA

) ss.

Court File No. 4-94-CV-875

Wanda M. Cotton, being first duly sworn, deposes and states that on the 22nd day of July, 1996, she caused a true and correct copy of the attached Defendants' Reply to Memorandum of Augustine Medical, Inc. in Opposition to Defendants' Motion for Partial Summary Judgment to be served via messenger upon Timothy M. Kenny, Esq., attorneys for plaintiff, at Oppenheimer, Wolff & Donnelly, 3400 Plaza VII Building, 45 South 7th Street, Minneapolis, Minnesota, 55402.

Sande M. Catton

Subscribed and sworn to before me this 22nd day of July, 1996.

Notary Public

TAM/jiv AMENDMENT USPTO October 31, 1342-119 AND date Petition for Extension o a check for \$465.00 Information Disclosure PTO Form 1449 (1 pg.) a check for \$230.00 Terminal Disclaimer () a check for \$55.00 S.D. Augustine, et augustine MEDICAL, 08/419,719
April 10, 1995 REQUEST stamp hereon FOR RECONSIDERATION The USPTO date stamp hereon acknowledges receipt of: MENDMENT AND REQUEST FOR RECONSIDERATION for "Thermal Blanket" ٥f PPAicant: S.D. Augustine, et al. ssignee: AUGUSTINE MEDICAL, INC. 2 erial No.: 08/419,719 iled: April 10, 1995 closures: Petition for Extension of Time (2 pgs.) (in dup) Sparie Pro a check for \$465.00 Partition of Time (2 pgs.) (in dup) a check for \$465.00 Partition Discussive Contement (2 pgs. & copy) PTO Form 1449 (1 pg cited references a check for \$230.00 NO) cited references والمعارض والمناجر وأماعي Terminal Disclaimer 413 p.55 a check for \$5.001996 led: October 31, 1996 /jiv 1342-119 للسماء ويعاليه فالمناجرين

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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)
S.D. AUGUSTINE, ET AL.	) Group Art Unit: 3304
Serial No.: 08/419,719	)
Filed: April 10, 1995	) Examiner: M. Graham
For: <u>INFLATABLE LOWER BODY</u> THERMAL BLANKET (As Amend	) ed) )
Assistant Commissioner for Patents Washington, D.C. 20231	
Sir:	CERTIFICATE OF MAILING 37 C.F.R. 1.8  I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date below:    10/31/96   Temmed A. Mead
	Date Signature

#### AMENDMENT AND REQUEST FOR RECONSIDERATION

In response to the Office Action dated May 2, 1996, please amend this application as follows:

#### IN THE SPECIFICATION

Page 1, line 8, please insert the following paragraph:

--This application is related to copending U.S. Patent Applications 08/386,324; 08/388,730; and 08/419,718.--

#### IN THE TITLE

Please amend the title at page 1, line 1 and page 33, line 1 as follows:

# INFLATABLE LOWER BODY THERMAL BLANKET

#### IN THE CLAIMS

Please amend the claims as follows:

1	26. (Amended) An inflatable thermal blanket for covering and bathing a
2	portion of a patient's body with thermally-controlled air, comprising:
3	a flexible base sheet having a first end forming a first end of the
4	thermal blanket, a second end forming a second end of the thermal blanket,
5	two edges forming respective edges of the thermal blanket, and an
6	undersurface forming an undersurface of the thermal blanket;
7	the first end, the second end, and respective edges of the base sheet
8	forming a periphery of the thermal blanket;
9	the base sheet including a first layer of flexible material and a
10	second layer of plastic material co-extensive with, and laminated to, the
11	first layer of flexible material;
12	an overlying flexible material sheet attached to the layer of plastic
13	material by a plurality of seals to form the base sheet and the overlaying
14	sheet into an inflatable covering [which has a plurality of interconnected
15	inflatable chambers];

16	a seal between the overlaying material sheet and the base sheet
17	around the periphery;
18	said inflatable [chambers in said] covering for substantially
19	longitudinal disposition over a portion of said [a] patient's body extending
20	substantially from the pelvic area of said patient's body to the feet of said
21	patient's body;
22	an inflating inlet for admitting thermally controlled air into the
23	inflatable [chambers to inflate the] covering;
24	a plurality of apertures opening through the base sheet into the
25	inflatable covering [chambers] for exhausting thermally controlled air from
26	the [inflatable chambers through the base sheet in response to inflation and
27	erection of the] inflatable covering; and
28	[a seal between the overlaying material sheet and the base sheet
29	around the periphery]
30	a non-inflatable foot extension formed in the inflatable covering at
31	the second end for covering and warming said patient's feet.
1	27. (Amended) The inflatable thermal blanket of Claim 26, wherein said
2	thermal blanket is self-erecting [further including a non-inflatable foot extension formed
3	in the inflatable covering at the second end for enclosing and warming a patient's feet in
4	response to inflation of the inflatable covering].

1	28. (Amended) The inflatable thermal blanket of Claim 26 [27], wherein the
2	non-inflatable foot extension comprises the non-inflatable extension of the inflatable
3	covering beyond the second end.
1	29. (Amended) The inflatable thermal blanket of Claim 26 [27], wherein the
2	non-inflatable foot extension includes an extension of the base sheet beyond the second
3	end.
1	30. (Amended) The inflatable thermal blanket of Claim 26 [27], wherein the
2	plurality of seals are discontinuous elongate seams formed between the overlaying material
3 .	sheet and the sheet of plastic material.
1	31. (Amended) The inflatable thermal blanket of Claim 30, wherein the
2	discontinuous elongate seams form the overlaying material sheet into a [the] plurality of
3	inflatable chambers, the plurality of inflatable chambers including parallel, communicating
4	tubular chambers.
1	32. (Amended) The thermal blanket of Claim 30, wherein the non-inflatable

foot extension includes an extension of the base sheet beyond the second end.

1	33. (Amended) A thermal care system including the inflatable therma
2	blanket of Claim 26 [27], and further including:
3	a heater/blower assembly for providing a source of heated air; and
4	a connecting hose coupled to the heater/blower assembly and to the inflating inle
5	for conducting heated air from the heated/blower assembly into the inflatable covering.

34. (Amended) A method of warming a patient [person] using a thermal
blanket including an inflatable space formed between a flexible base sheet and an
overlaying material sheet attached to the base sheet by a peripheral seal around the
periphery of the thermal blanket and a plurality of seals inside the periphery of the
thermal blanket [that form the base sheet and overlaying material sheet into an inflatable
covering with a plurality of interconnected inflatable chambers], a non-inflatable section
formed in a portion of the inflatable thermal blanket, and apertures that open into the
inflatable space through the flexible base sheet for exhausting air from the inflatable
space, the method comprising the steps of:
disposing the thermal blanket to substantially longitudinally dispose the
inflatable space [chambers] over a portion of a patient's body extending

disposing the thermal blanket to substantially longitudinally dispose the inflatable space [chambers] over a portion of a patient's body extending substantially from the pelvic area of said patient's body to the feet of said patient's body, with the non-inflatable section disposed over the patient's feet; inflating the thermal blanket with warmed air; [and] exhausting warmed air through the apertures in the flexible sheet; and

using the non-inflatable section, retaining heat under the thermal blanket near the patient's feet.

	35.	(Amended)	The	method	of	Claim	34,	wherein	the	thermal	blanket
[furth	er inclu	des a non-infla	table	section f	orm	ed in a	por	tion of th	e pe	riphery o	f the] <u>is</u>
a self	erecting	g thermal blank	et, th	e method	d fu	rther co	mpr	ising the	step	[s] of:	

[the non-inflatable section forming a non-inflatable foot drape in the thermal blanket during the inflating step; and

using the non-inflatable foot drape, trapping and retaining the heat under the thermal blanket during the exhausting step]

the inflatable thermal blanket self-erecting in the step of inflating.

#### REMARKS

Claims 26-31 and 33-35 have been amended. Claims 26-35 remain in the application.

A Petition for Extension of Time for Three Months accompanies this paper, together with a check to cover the requested extension.

A Terminal Disclaimer over U.S. Patent No. 5,184,612 is forwarded herewith, together with a check to cover the required terminal disclaimer fee.

An Information Disclosure Statement with the required fee also accompanies this paper.

The Examiner has rejected Claims 26-33 for obviousness-type double patenting over Claims 1-20 of U.S. Patent No. 5,184, 612. The Terminal Disclaimer accompanying this paper obviates the basis for this rejection and the Examiner is respectfully requested to remove it.

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The Examiner has rejected Claim 34 for being anticipated by Augustine '188. Claim 34 has been amended to incorporate limitations respecting a non-inflatable extension for covering the feet. The Augustine '188 patent includes no such element and therefore does not anticipate Claim 34 as amended. Therefore, the Examiner is respectfully requested to withdraw this rejection.

In view of the amendments and remarks made in this paper and further in view of the Terminal Disclaimer accompanying this paper, it is submitted that all claims in this application are allowable over the prior art that is of record in this application.

Respectfully submitted,

Terrance A. Meador

Attorney for Applicant(s) Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 "B" Street, Suite 3100 San Diego, California 92101

Telephone: (619) 233-9004

"PATENT"

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)		~
S.D. AUGUSTINE, ET AL.	) Gro	up Art Unit:	3304
Serial No.: 08/419,719	)		
Filed: April 10, 1995	) Exa	miner: M.	Graham
For: <u>INFLATABLE LOWER BODY</u> THERMAL BLANKET (As Amen	) led) )		
Assistant Commissioner for Patents Washington, D.C. 20231			
Sir:		CATE OF MAILING	dete-de-steel

the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date below:

#### PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(c)

Applicant hereby petitions for a three month Extension of Time to respond to the Office Action mailed May 2, 1996, thereby extending the time to respond from August 2, 1996 to and including November 2, 1996.

Transmitted herewith is a Amendment and Request for Reconsideration in response to the Office Action.

Also transmitted herewith are a Terminal Disclaimer and an Information Disclosure Statement, PTO Form 1449 and the cited references.

A check in the amount of \$465 is enclosed herewith to cover the applicable fee for a three month extension of time as set forth in 37 CFR 1.17(c). Please charge any deficit or credit any excess to our Deposit Account No. 02-0460. Two copies of this letter are enclosed.

Respectfully submitted,

Terrance A. Meador Attorney for Applicant(s)

Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 "B" Street, Suite 3100 San Diego, California 92101

Telephone: (619) 233-9004

"PATENT"

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re A	pplicat	ion of:	)			
S.D. A	ugus'	TINE, ET AL.	)	Group Art U	nit:	3304
Serial N	۷o.:	08/419,719	)			
Filed:		April 10, 1995	)	Examiner:	M. G	raham
		TABLE LOWER BODY MAL BLANKET (As Amended)	)			

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

#### CERTIFICATE OF MAILING

37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington,

# PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(c)

Applicant hereby petitions for a three month Extension of Time to respond to the Office Action mailed May 2, 1996, thereby extending the time to respond from August 2, 1996 to and including November 2, 1996.

Transmitted herewith is a Amendment and Request for Reconsideration in response to the Office Action.

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Also transmitted herewith are a Terminal Disclaimer and an Information Disclosure Statement, PTO Form 1449 and the cited references.

A check in the amount of \$465 is enclosed herewith to cover the applicable fee for a three month extension of time as set forth in 37 CFR 1.17(c). Please charge any deficit or credit any excess to our Deposit Account No. 02-0460. Two copies of this letter are enclosed.

Respectfully submitted,

Terrance A. Meador

Attorney for Applicant(s) Registration No. 30,298

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Telephone: (619) 233-9004

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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applica	ation of:	)			
S.D. AUGUS	STINE, ET AL.	)	Group Art U	nit:	3304
Șerial No.:	08/419,719	) )			
Filed:	April 10, 1995	) )	Examiner:	M. G	aham
	ATABLE LOWER BODY RMAL BLANKET (As Amended)	) )			

Assistant Commissioner for Patents Washington, D.C. 20231

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Date Signatur

#### INFORMATION DISCLOSURE STATEMENT

Applicant hereby cites the prior art listed in accompanying Form PTO-1449 with respect to the above-referenced patent application under the provisions of 37 C.F.R., Sections 1.56, 1.97 and 1.98. Copies of the documents are attached.

The filing of this Information Disclosure Statement will not be construed to mean that a search was conducted or that no other material information, as defined by 37 C.F.R. 1.56, exists.

Submitted herewith are a Deposition of Randall C. Arnold, a co-inventor in this application, and 4 of 5 exhibits that are cited in the Deposition.

The Examiner is urged to consider the entire deposition; however, the applicants respectfully draw the Examiner's attention to Pages 31 and 32, where reference is made to the annual meeting of the American Society of Anesthesiologists that was held in New Orleans in September, 1989.

Reference is also made to pages 37-40 where Exhibits 1,2, and 3 are explained and a "lower body OR surgical blanket" is mentioned.

Reference is also made to pages 101-104 where certain features of the lower body OR surgical blanket are discussed.

The Examiner is respectfully requested to make the listed documents of record in connection with the prosecution of the subjection application.

Respectfully submitted,

Terrance A. Meador Attorney for Applicant(s)

Registration No. 30,298

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In re Application of:	)		٠.
S.D. AUGUSTINE, ET AL.	) }	Group Art U	nit: 3304
Serial No.: 08/419,719	)		
Filed: April 10, 1995	)	Examiner:	M. Graham
For: <u>INFLATABLE LOWER BOD</u> THERMAL BLANKET (As A			
Assistant Commissioner for Patents Washington, D.C. 20231			
Sir:	I hereby certify the U.S. Postal-	Service as First Clas sistant Commissioner fo	is being deposited with s Mail in an envelope or Patents. Washington

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Telephone: (619) 233-9004

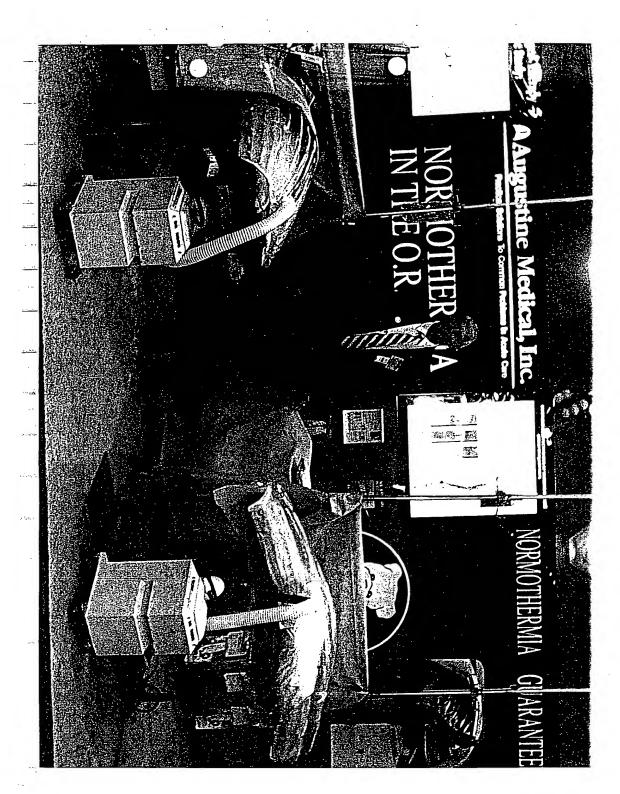
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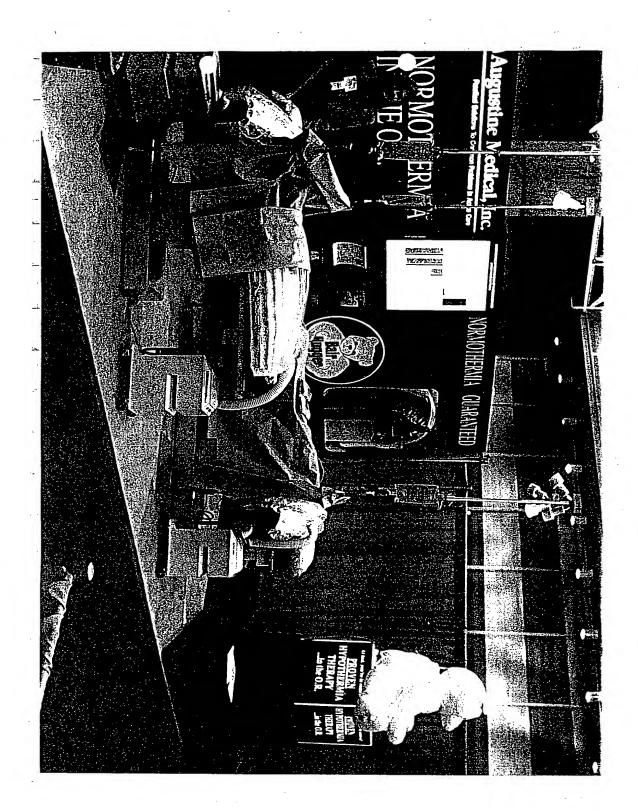
Docket No. 1342-119	Application No. 08/419,719				
Applicant: S.D. Augustine et al					
	0 4 41-14 2204				

IN AN APPLICATION  (Use Several Sheets If Necessary)			Applicant: S.D. Augustine et al								
			Filing Date: Apr	il 10, 1995	Group Art Un	Art Unit 3304					
			U.S. PATENT	DOCUMENTS							
EXAMINER INITIAL	DOCUMENT NUMBER	MENT NUMBER DATE		AME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE				
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	Deposition of Ran District of Missou	Deposition of Randall C. Arnold in <u>Mallinckrodt Medical, Inc. v. Augustine Medical, Inc.</u> , Case No. 4:95CV00514 LOD, Eastern District of Missouri, Eastern Division, February 27, 1996									
	Photograph Exhibi	Photograph Exhibit No. 1 of Deposition of Randall C. Arnold									
	Photograph Exhibi	Photograph Exhibit No. 2 of Deposition of Randall C. Arnold									
	Photograph Exhibi	Photograph Exhibit No. 3 of Deposition of Randall C. Arnold									
	"Normothermia In	"Normothermia In The O.R.", Exhibit No. 4 of Deposition of Randal C. Arnold									
EXAMINER		0				DATE CONSIDERED					
CYAMINER: I	nitial if citation is considered	whether or not	citation is in cor	formance with MPI	FP § 609: Dray	v line through cit	ation if not in	conformance			

and not considered. Include copy of this form with next communication to the applicant.

(2/92 PTO)



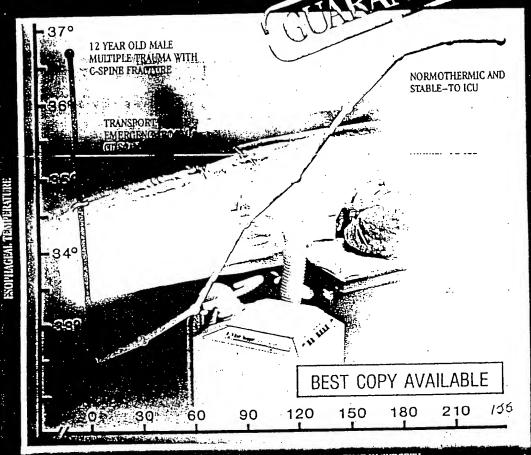


8 -



AUGUSTINE MEDICAL INTRODUCES...

# NORMOTHERMIA IN THE O.R.



TIME IN SURGERY



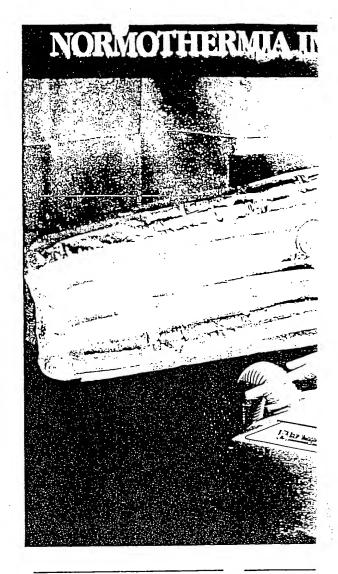
BAIR HUGGER™ CONVECTIVE WARMING THERAPY™ STARTED IN O.R.

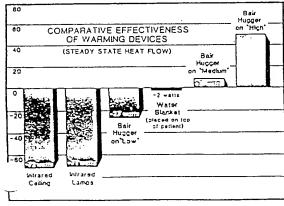
#### AT LAST, YOU'RE IN CONTROL!

Augustine Medical guarantees that Bair Hugger "Convective Warming Therapy will intain normothermia in the O.R. Far too en patients become seriously hypothermic despite the physicians best efforts. In fact, studies show that 60%-80% of all O.R. patients are hypothermic when treated with the traditional "warming" devices, which are virtually ineffective. Bair Hugger Convective Warming Therapy has actively warmed over 150,000 hypothermic PACU patients in its first year of use. It's effectiveness has been documented in several clinical studies. The proven effectiveness of Bair Hugger Therapy establishes a new standard of care. With Bair Hugger Convective Warming Therapy, hypothermia in the O.R. is a problem of the past, guaranteed!\*

# Bair Hugger Convective Warming Therapy is the Only Proven Method of Active Surface Warming.

All of the available methods of surface warming were tested for effectiveness at the University of California-San Francisco. Using heat flux transducers in a controlled laboraty setting, Dr. Dan Sessler found that only air Hugger Therapy actively transfers heat to the patient. "... (Bair Hugger Therapy) provided enough heat to increase body temperature almost 3°C per hour." The other technologies did not transfer heat to the patient and in fact could not even prevent the patients from losing their endogenous heat."





"The Bair Hugger" is the first device that allows you to choose your patient's temperature and keep them there. We've had control of blood pressure and pulse for years, now we can finally control temperature."

Neil Feinglass, M.D., Jacksonville, FL

"Bair Hugge: Body Hear"

> - Ameri Anesii Annuu







#### its Loss of

of oress release, Orleans, LA, 1989 "The injured patient arrived in the O.R. cold and bradycardic. Active warming with the Bair Hugger." resulted in a rapid improvement of the temperature and stabilization of the heart rate."

-K.G. Belani, M.D., Minneapolis, MN

## Bair Hugger Warming Covers are Available in Two Styles

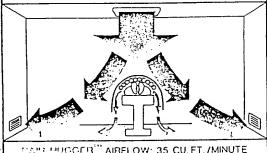
A chest/arm Cover for abdominal and lower extremity operations and a leg Cover for abdominal, thoracic and intracranial operations.

#### Localized Air Flow

The combination of the Steridrape (3M, St. Paul, MN) barrier design and the overlaying surgical drape, prevents the warm exhaust air from migrating toward the surgical incision. The heated air flows from under the surgical drape toward the floor. It is then carried directly toward the room exhaust vents by the large volume of room ventilation air which is blowing directly down on the patient from the ceiling.

The warm air contributes less than 3% of the total air circulation in the O.R. and is undetectable at the surgical site. Bair Hugger air is filtered through a 0.2 micron filter before heating.

O.R. AIRFLOW IN THE OPERATING ROOM AIRFLOW: 1,300 - 26,000 CU.FT./MINUTE VELOCITY: 20 - 200 LIN.FT./MINUTE



TYPE HUDGERS AIRPLOW: 35 CU.FT./MINUTE VELOCITY: 3 LIN.FT./MINUTE IN 1.275 OF TOTAL AIRPLOW DIRECTED AWAY FROM THE INCISION)

**NVECTIVE WARMING THERAPY**"



# Bair Hugger" Convective Warming Therapy is:

fe Convective Warming is as safe as aning up the rexxn temperature. In conust, water based warming technologies uch as water mattresses and heated umidifiers have caused numerous cases (full thickness burns and tracheal amage."

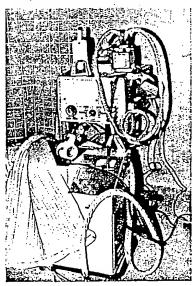
Convenient The Bair Hugger Parming System can also warm I.V. fluids nd blood! Up to one liter/hour of room emperature fluid can be warmed by simly adding two lengths of extension abing to the LV line and placing them serveen the warm air tubes of the Cover.

ip to three liters/hour of cold blood can e warmed with a Bair Hugger" Fluid Varming Cassette which is inserted no the center air tube. Traditional fluid varmers allow the fluid to cool during he six foot transit to the patient. The Bair fugger System keeps the fluid warm ight up to the LV site. Bair Hugger fluid varming is inexpensive, efficient and educes equipment needs.

Cost Effective Our simple and afe warming therapy eliminates any need or water mattresses and airway heaters. for humidification of the tracheal nucosa, we do recommend the use of an "rtificial nose" (airway Heat and Mois-

· Exchanger). The Bair Hugger fluid ming capability makes blood/fluid warmers unnecessary in all but the very large volume resuscitations.

Practical Buir Hugger Convective Warming Therapy consists of a Heating Unit and a disposable Warming Cover that directs a gentle flow of warm air across the patient's body which provides for



Bair Hugger<sup>18</sup> Therapy allows you the freedom to concentrate on the patient, not on the equipmenti

safe and effective warming. The Bair Hug-ger Heating Unit uses a reliable, high efficiency blower, a sealed 850 Watt heating element, and a microprocessor based temperature controller to create a con-tinuous flow of warm air. The patented Warming Cover is made of a layer of plastic and a layer of tissue paper/plastic aminate, bonded together into long tubular channels. When inflated, the selfsupporting Warming Cover is designed to arch over the patient's body, creating a warm "coccoon". The warm air exits through microperforations in the Cover's underlayer, resulting in convective warming as it surrounds the patient.

Free Trial If you are interested in effective, safe and convenient patient warming, a free trial of Bair Hugger Con-vective Warming Therapy can quickly be arranged. Just call us toll free at:

1-800-733-7775 or (612) 941-8866

\*Terms of quarantee:

Bair Hugger " Convective Warming Therapy " must begin immediately after induction of anesthesia on the "high" setting and continue throughout the case II indicated.

Infused blood and fluids must be warmed to body

If these two criteria are met and the nationt is hypothermic at the end of the operation (core temperature 35°C). Augustine Medical will replace the Warming Cover. This guarantee is limited to the replacement of the Warming Cover.

SPECIFICATIONS HEAT/BLOWER UNIT

Size:

Weight: Power Requirements: Temperature Range: Enclosure:

Power Cable: Filter:

Covers

Arm Cover Size: Leg Cover Size: Weight: Material:

WEH UNII
23° high × 16° deep × 14° wide
32 lbs
110 VAC
Ambient to 110°F Max
Enameled Steel
14 Feet Long
High efficiency 0.2 air filter

82" × 20" 32" × 36" 6 ounces Polyethylene and tissue paper laminate.



AUGUSTINE MEDICAL INC.

PRICTICAL SOLUTIONS TO COMMON PROBLEMS IN ACUTE CARE-10393 West 70th Street • Eden Prairie, Minnesota 55344 Phone: 1-800-733-7775

BEST COPY AVAILABLE

(1) Yauchn MN, et al: Anesth Anal 50:746-75), 1981. (2) Sessier D, et al: One Presentation American Society of Anesthesiologists Annual Meeting, New Orients, LA 1999 (In Press).
(3) Horre RH, et al: Anesthesiology 30: 408-41), 1972. (e) Code ML, et al: Aniation, Space & Environ Med 48:025-032, 1972. (5) Sessier D, et al: Aniasthesiology 71:ANII, 1982. (e) Control ML, et al: Aniation, Space & Environ Med 48:025-032, 1972. (f) Sessier D, et al: In Interest 1980, (f) Sessier D, et al: In Interest 1980, (f) Sessier D, et al: Interest 1980, (f) Sessier D, et al: Interest 1980, (f) Sessier D, et al: Interest 1980, (f) Sessier D, et al: Interest 1980, (f) Sessier D, et al: Interest 1980, (f) Sessier D, et al: Interest D, et al: Interest 1980, (f) Sessier D, et al: Interest D, et al: Interest 1980, (f) Sessier D, et al: I

#### "PATENT"

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

S.D. Augustine et al ) Group No.: 3304	`
Serial No.: 08/419,719 ) ) Examiner: M. Graha	am
Filed: April 10, 1995	
For: THERMAL BLANKET )	

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

Dear Sir:

#### TERMINAL DISCLAIMÉR

Your Petitioner, AUGUSTINE MEDICAL, INC., represents that:
by virtue of an Assignment recorded in the United States
Patent Office on 6/25/92, at Reel 6147, Frame 0720, it is the
owner of the entire right and interest in United States Patent
5,184,612, which issued February 9, 1993;

by virtue of an Assignment recorded in the United States Patent Office on 2/23/90 at Reel 5244, Frame 0712 it is the owner of the entire right and interest in United States Patent Application Serial No. 07/227,189 (abandoned);

F:\WP60\USERS\CLARE\AUGUSTIN\1342-119.TDC

by virtue of an Assignment recorded in the United States Patent Office on 8/31/90 at Reel 5427, Frame 0875, it is the owner of the entire right and interest in United States Patent Application No. 07/550,757 (a continuation-in-part of United States Serial No. 07/227,189, and now abandoned); and

by virtue of an Assignment recorded in the United States Patent Office on 4/13/92 at Reel 6082, Frame 0560, it is the owner of the entire right and interest in United States Patent Application Serial No. 07/638,748 (a continuation-in-part of United States Serial No. 07/550,757, and now United States Patent No. 5,405,371), and thereby the owner of the entire right and interest in this patent application, United States Patent Application Serial No. 08/419,719 (a continuation of United States Serial No. 07/638,748).

Your petitioner, AUGUSTINE MEDICAL, INC., hereby disclaims the terminal part of any patent granted on United States Patent Application Serial No. 08/419,719 which would extend beyond the expiration date of United States Patent 5,184,612 and hereby agrees that any patent so granted on United States Patent Application Serial No. 08/419,719 shall be enforceable only for and during such period that the legal title to said patent shall be the same as the legal title to United States Patent 5,184,612, this agreement to run with any patent granted on United States Patent Application Serial No. 08/419,719 and to be binding upon the grantee, its successors or assigns.

I have reviewed the evidentiary documents concerning ownership of United States Patent 5,184,612 and United Application Serial No. 08/419,719 and, to the best of my knowledge and belief, they establish the entire right, title, and interest to United States Patent 5,184,612 and to United States Patent Application Serial No. 08/419,719 in AUGUSTINE MEDICAL, INC.

I, JOHN E. THOMAS, am President of AUGUSTINE MEDICAL, INC., and I am authorized to sign this Terminal Disclaimer on behalf of AUGUSTINE MEDICAL, INC.

5/22/96

JOHN E. THOMAS, President AUGUSTINE MEDICAL, INC. TO: TERRANCE A. MEADOR
BAKER, MAXHAM, JESTER & MEADOR
SUITE 1202
110 WEST "C" STREET
SAN DIEGO, CA 92101

RECEIVED

MAY 03 1990

Saker, Maxham, Jester & Messier

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ASSIGNOR: OO2 AUGUSTINE, DOUGLAS J.

DOC DATE: 02/07/90 DOC DATE: 02/07/90

RECORDATION DATE: 02/23/90 NUMBER OF PAGES 001 REEL/FRAME 5244/0712

DIGEST: ASSIGNMENT OF ASSIGNORS INTEREST

ASSIGNEE: 501 AUGUSTINE MEDICAL, INC., 10393 WEST 70TH STREET, SUITE 10 O, EDEN PRAIRIE, MN A CORP. OF MN

SERIAL NUMBER 7-227189 FILING DATE 08/02/88 PATENT NUMBER 1 ISSUE DATE 00/00/00

TITLE OF INVENTION: THERMAL BLANKET

- INVENTOR: OO1 AUGUSTINE, SCOTT D. INVENTOR: OO2 AUGUSTINE, DOUGLAS J.

#### ASSIGNMENT

WHEREAS, SCOTT D. AUGUSTINE, 9017 Cavell Circle, Bloomington, Minnesota, 55438, and DOUGLAS J. AUGUSTINE, 18546 Avon Court, Eden Prairie, Minnesota, 55346, hereinafter referred to as Assignors have acquired rights to a certain invention and a United States patent application covering the same; and

WHEREAS, in accordance with the terms of an agreement dated 7/15/87, the Assignors have agreed with AUGUSTINE MEDICAL, INC., a corporation of the State of Minnesota, having a principal place of business at 10393 West 70th Street, Suite 100, Eden Prairie, Minnesota, 55344, hereinafter referred to as the Assignee, the Assignors have agreed to assign these rights to the Assignee; and

NOW, THEREFORE, be it known that for good and valuable consideration, the Assignors do hereby formally grant, bargain, sell, transfer, convey and assign to the Assignee, its successors, legal representatives or assigns, the entire right, title, and interest in and to United States Patent Application Serial No. 07/227,189, filed August 2, 1988 and entitled "THERMAL BLANKET", and all continuations and divisions thereof, said U.S. Patent Application to be held and enjoyed by the Assignee for its own use and enjoyment and for the use and enjoyment of its successors, assigns or other legal representatives as fully and entirely as the same would have been held and enjoyed by the Assignors had this Assignment not been made.

The Assignors covenant that they have the right to grant this Assignment.

Executed at Eden Prairie, Minnesota, this 7 day of February, 1990.

SCOTT D. AUGUSTINE

OUGEAS J./AUGUSTINE

Witness: Tenano A. Mlado

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UNITED STATES DEF ... MENT OF COMMERCE Patent and Trademar, Office

ASSISTANT SECRETARY . J COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

, Maxham, Jester & Meedor

: TERRANCE A. MEADOR BAKER, MAXHAM, JESTER & MEADOR 110 WEST "C" ST,. STE. 1202 SAN DIEGO, CA 92101

> UNITED STATES PATENT AND TRADEMARK OFFICE NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

E ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF E U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AILABLE AT THE U.S. PATENT AND TRADEMARK OFFICE ON THE REEL AND FRAME -MBER REFERENCED BELOW. A DIGEST OF THE DOCUMENT HAS ALSO BEEN MADE D APPEARS IN THE OFFICE'S RECORDS AS SHOWN:

SIGNOR: OO1 AUGUSTINE, SCOTT D. SIGNOR: 002 ARNOLD, RANDALL C.

DOC DATE: 08/21/90 DOC DATE: 08/22/90

CORDATION DATE: 08/31/90 NUMBER OF PAGES 003 REEL/FRAME 5427/0875

GEST: ASSIGNMENT OF ASSIGNORS INTEREST

ISIGNEE: 501 AUGUSTINE MEDICAL, INC., 10393 WEST 70TH ST., STE. 100, E IN PRAIRIE, MN 55344

RIAL NUMBER ITENT NUMBER

7-550757

FILING DATE 07/10/90 ISSUE DATE 00/00/00



BAKER, MAXHAM, JESTER & MEADOR

ATTORNEYS AT LAW
SUITE 1202
110 WEST "C" STREET
SAN DIEGO, CALIFORNIA 92101
(619) 233-9004
FACSIMILE (619) 544-1246

PATENTS
TRADEMARKS COPYRIGHTS
NORTH COUNTY OFFICE
HIT PALOMAR AIRPORT PC:
SUITE 330
CARLSBAO, CA 92009

(619) 438-3007

TER W. DUFT

HAEL H. JESTER

RANCE A. MEADOR

August 28, 1990

Hon. Commissioner of Patents and Trademarks Washington, D. C. 20231

Dear Sir:

Enclosed please find an Assignment from SCOTT D. AUGUSTINE, and RANDALL C. ARNOLD to AUGUSTINE MEDICAL, INC., for U.S. Patent Application Serial No. 07/550,757, filed July 10, 1990, for "THERMAL BLANKET".

Kindly record the enclosed Document and return it to the undersigned.

Our check in the amount of \$8.00 is enclosed for the recordal fee. If any additional fees arise in connection with this recording which are not covered by the money enclosed, please charge such fees, or credit any overpayment, to Deposit Account No. 02-0460. A duplicate copy of this letter is enclosed.

Very truly yours,

BAKER, MAXHAM, JESTER & MEADOR

TERRANCE A. MEADOR

Registration No. #30,298

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#### ASSIGNMENT

#### TO WHOM IT MAY CONCERN

For valuable consideration, be it known that we, SCOTT D. AUGUSTINE, 9017 Cavell Circle, Bloomington, Minnesota, 55438, and RANDALL C. ARNOLD, 1701 Payne Avenue, Maplewood, Minnesota, 55117, have sold, assigned and transferred and by these presents do sell, assign, transfer and set over unto AUGUSTINE MEDICAL, INC., 10393 West 70th Street, Suite 100, Eden Prairie, Minnesota, 55344, its successors, legal representatives, or assigns, our whole right, title and interest, in and to a certain invention relating to "THERMAL BLANKET" and United States Patent Application therefor, Serial No. 07/550,757, filed in the United States Patent and Trademark Office on July 10, 1990, and all original and reissue patents granted thereof, and all divisions and continuations thereof, including the subject matter of any and all claims in every such patent, and all foreign rights to said invention, and covenant that we have full right to do so, and agree that we will communicate to said AUGUSTINE MEDICAL, IN., or its representatives all facts known to us respecting said invention, whenever requested, and testify in any legal

proceedings, sign all lawful papers, make all rightful oaths and generally do everything possible to aid said AUGUSTINE MEDICAL, INC., its successors, assigns, and nominees, to obtain and enforce proper patent protection for said invention in the United States of America and throughout the World.

The Commissioner of Patents and Trademarks is requested to issue the Letters Patent which may be granted for said invention or any part thereof unto said AUGUSTINE MEDICAL, INC., in keeping with this Assignment.

Dated: 8/21/90

SCOTT D. AUGUSTIN

Dated: 8/22/90

RANDALL C. ARNOLD

Dated: 8-22-90

RECORDED
PATENT AND TRADEMARK
OFFICE

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UNITED STALES DEPARTMENT OF COMMERCE Patent and T demark Office
ASSISTANT SEC ARY AND COMMISSIONER

OF PATENTS AND TRADEMARKS Washington, D.C. 20231

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JUN 01 1992

DATE: 05/11/92 TO: TERRANCE A. MEADOR BAKER, MAXHAM, JESTER & MEADOR 750 B STREET, SE. 2770

SAN DIEGO, CA 92101

UNITED STATES PATENT AND TRADEMARK OFFICE NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

E ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF E U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS 'AILABLE AT THE U.S. PATENT AND TRADEMARK OFFICE ON THE REEL AND FRAME IMBER REFERENCED BELOW.

EASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION INTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE TENT ASSIGNMENT PROCESSING SYSTEM. IF YOU SHOULD FIND ANY ERRORS, ON IIS NOTICE, PLEASE SEND A REQUEST FOR CORRECTION TO: U.S. PATENT AND VADEMARK OFFICE, ASSIGNMENT BRANCH, NORTH TOWER BUILDING, SUITE 10C35, ASHINGTON, D.C. 20231

SIGNOR:

DOC DATE: 01/07/91

AUGUSTINE, SCOTT D.

DOC DATE: 01/07/91

SSIGNOR: ARNOLD, RANDALL C.

REEL/FRAME 6082/0560 ECORDATION DATE: 04/13/92 NUMBER OF PAGES 003

IGEST : ASSIGNMENT OF ASSIGNORS INTEREST

SSIGNEE:

AUGUSTINE MEDICAL, INC. 10393 WEST 70TH STREET, STE. 100, EDEN PRAIRIE, MN 55344

FILING DATE 01/08/91 7.-638748 ERIAL NUMBER 00/00/00 ATENT NUMBER ISSUE DATE



RELING E. B AWRENCE AL TOTAL

BAKER, MAXHAM, JESTER & ME. DOR A PROFESSIONAL LAW CORPORATION

> SYMPHONY TOWERS SAN DIEGO, CALIFORNIA 92101 FACSIMILE (619) \$44-1246

PATÉNTS TRADEMARKS COPYRIGHTS

ALTER W. DUFT IMES A. WARD

April 10, 1992

Hon. Commissioner of Patents and Trademarks Washington, D. C. 20231

Re: Assignment Recordal Request for U.S. Patent Application for "THERMAL BLANKET"

Our Ref.: 1342 35

Dear Sir:

Enclosed please find an Assignment from SCOTT D. AUGUSTINE and RANDALL C. ARNOLD, to AUGUSTINE MEDICAL, INC., for U.S. Patent Application Serial No. 07/638,748, filed January 8, 1991, for "THERMAL BLANKET".

Kindly record the enclosed Document and return it to the undersigned.

Our check in the amount of \$40.00 is enclosed for the recordal fee. If any additional fees arise in connection with this recording which are not covered by the money enclosed, please charge such fees, or credit any overpayment, to Deposit Account No. 02-0460. A duplicate copy of this letter is enclosed.

Very truly yours,

BAKER, MAXHAM, JESTER & MEADOR

Registration No. #30,298

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TAM/cmr Enclosures

050 LP 04/17/92 07638748

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#### ASSIGNMENT

#### TO WHOM IT MAY CONCERN

For valuable consideration, be it known that we, SCOTT D. AUGUSTINE, 9017 Cavell Circle, Bloomington, Minnesota, 55438, and RANDALL C. ARNOLD, 1701 Payne Avenue, Maplewood, Minnesota, 55117, have sold, assigned and transferred and by these presents do sell, assign, transfer and set over unto AUGUSTINE MEDICAL, INC., 10393 West 70th Street, Suite 100, Eden Prairie, Minnesota, 55344, its successors, legal representatives, or assigns, our whole right, title and interest, in and to a certain invention relating to "THERMAL BLANKET" and United States Patent Application therefor, executed on even date herewith, and all original and reissue patents granted thereof, and all divisions and continuations thereof, including the subject matter of any and all claims in every such patent, and all foreign rights to said invention, and covenant that we have full right to do so, and agree that we will communicate to said AUGUSTINE MEDICAL, INC., or its representatives all facts known to us respecting said invention, whenever requested, and testify in any legal

proceedings, sign all lawful papers, make all rightful oaths and generally do everything possible to aid said AUGUSTINE MEDICAL, INC., its successors, assigns, and nominees, to obtain and enforce proper patent protection for said invention in the United States of America and throughout the World.

The Commissioner of Patents and Trademarks is requested to issue the Letters Patent which may be granted for said invention or any part thereof unto said AUGUSTINE MEDICAL, INC., in keeping with this Assignment.

Dated: < 1/7/91

SCOTT D. AUGUSTINE

Dated: \* 1/7/9/

RANDALL C. ARNOLD

Dated: 💌 Tiliun 91

WITNESS W.

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#### Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST	NAMED INVENTOR		ATTORNEY DOCKET NO.
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Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

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**DOCKETED** 

2 - Mail Copy

### Office Action Summary

Application No. 08/419,719 Applicant(s)

Examiner

Augustine et al.

Merk S. Greham

Group Art Unit 3304



Responsive to communication(s) filed on 7/10/95, 10/12/95							
☐ This action is FINAL.							
☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.							
A shortened statutory period for response to this action is set to expire month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).							
Disposition of Claims							
	is/are pending in the application.						
Of the above, claim(s)	is/are withdrawn from consideration.						
Claim(s)							
☐ Claims							
Application Papers  See the attached Notice of Draftsperson's Patent Drawing Review,	Application Papers						
☐ The drawing(s) filed onis/are objected to by the Examiner.							
☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.							
☐ The specification is objected to by the Examiner.							
☐ The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. § 119							
☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).							
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been							
received.							
received in Application No. (Series Code/Serial Number)							
received in this national stage application from the International Bureau (PCT Rule 17.2(a)).							
*Certified copies not received:							
Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).							
Attachment(s)							
Notice of References Cited, PTO-892	•						
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). ☐ Interview Summary, PTO-413	5						
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948							
□ Notice of Informal Patent Application, PTO-152							
SEE OFFICE ACTION ON THE FOLLOWING PAGES							

Serial Number: 08/419,719

Art Unit: 3304

Claims 26-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,184,612. Although the conflicting claims are not identical, they are not patentably distinct from each other because removal of the additionally claimed elements with their corresponding loss of function would have been obvious to one of ordinary skill in the art.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

The following is a quotation of the appropriate paragraphs of 35 U.S.C.  $\S$  102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 34 is rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Augustine '188.

Claim 35 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Serial Number: 08/419,719

Art Unit: 3304

Any inquiry concerning this communication should be directed to Mark S. Graham at telephone number (703) 308-1355.

MSG April 26, 1996

> MARKS GRAHAM MARKS GRAHAMER PRIMARY EXAMINER OROUP 3300

SHEET 1 OF 1 Form PTO-1449 Docket No. 1342-119 Application No. 08/419,719 INFORMATION DISCLOSURE CITATION Applicant: S.D. Augustine et al IN AN APPLICATION (Use Several Sheets If Necessary) Filing Date: 4/10/95 Group Art Unit 35504 U.S. PATENT DOCUMENTS EXAMINER FILING DATE INITIAL DOCUMENT NUMBER DATE NAME CLASS SUBCLASS IF APPROPRIATE 6/20/50 Williams 5 347 1/18/45 Months of the Section

XAMINER: Initial if exaction is considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

DATE CONSIDERED

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EXAMINER

DATE CONSIDERED/

(Form PTO-1449 [6-4])

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STATUS INQUIRY for "Thermal Blanket"

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Applicant: S.D. Augustine et al Augustine Medical, Inc. Assignee: 08/419,719

Serial No.: Filed: April 10, 1995

March /5, 1996 Mailed:

TAM/cmr 1342-119

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olicant: S.D. Augustine et al

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:ignee: Augustine Medical, Inc.

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March <u>15</u>, 1996 iled:

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#### "PATENT"

Group No.: 3304

Examiner: M. Graham

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

S.D. Augustine et al

Serial No.: 08/419,719

Filed: April 10, 1995

For: THERMAL BLANKET

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

Dear Sir:

CERTIFICATE OF FACSIMILE TRANSMISSION 37 C.F.R. 1.8

I hereby certify that this correspondence is being facsimile transmitted to: Commissioner of Patents and Trademarks,

3/15/96 Jenanc

#### **STATUS INQUIRY**

Applicants respectfully request that they be notified of the status of this application.

Respectfully submitted,

TERRANCE A. MEADOR Attorney for Applicant(s) Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 "B" Street, Suite 3100 San Diego, California 92101 Telephone: (619) 233-9004

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Patent and Trademark Office.

Address: Comissioner of Patents and Trademarks

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Below is a communication from the EXAMINER in charge of this application COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION
THE PERIOD FOR RESPONSE:
is extended to run from the date of the Final Rejection
continues to run from the date of the Final Rejection
expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for response expire later than six months from the date of the final rejection.
Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date that the shortened statutory period for response expires as set forth above.
Appellant's Brief is due in accordance with 37 CFR 1.192(a).
Applicant's response to the final rejection, filed, has been considered with the following affect, but it is not deemed to place the application in condition for allowance:
1. The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:
a. There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
b. They raise new issues that would require further consideration and/or search. (See Note).
c. They raise the issue of new matter. (See Note).
d.   They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
e.   They present additional claims without cancelling a corresponding number of finally rejected claims.
NOTE:
2. Newly proposed or amended claims would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.
3. Upon the filing of an appeal, the proposed amendment $\square$ will be $\square$ will not be, entered and the status of the claims in this application would be as follows:
Allowed claims:
Claims objected to:
Claims rejected:  However;
The rejection of claims on references is deemed to be overcome by applicant's response.     The rejection of claims on non-reference grounds only is deemed to be overcome by applicant's response.
4. The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection.
5. The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.
☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.
* New first action withdrawling finality of previous action will follow, All
OV S. GRAHAMER
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# BAKER, MAXHAM, JESTER & MEADOR

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BONDO: IN F. JOHNSTON N C LUMBERTSEN

SYMPHONY TOWERS 750 'B' STREET, SUITE 2770 SAN DIEGO, CALIFORNIA 92101 TEL (619) 233-9004 FACSIMILE (619) 544-1246

### こつかようひをかしてする ATTORNEY/CLIENT PRIVILEGED COMMUNICATION

(Please Call (619) 233-9004 If Received In Error)

DATE: October 12, 1995

TO:	Examiner M. Graham
COMPANY:	United States Patent and Trademark Office
FAX NO.:	703/305-3590
FROM:	T.A. Meador
RE:	08/419,719
Our Reference No.:	1342-119
NUMBER OF PAGES IN	CLUDING COVER SHEET: 11
lf transmission is poor, or ij as possible.	f you do not receive all pages, please call (619) 233-9004 as soon
COMMENTS:	

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#### "PATENT"

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	)
S.D. Augustine et al	) Group No.: 3304
Serial No.: 08/419,719	) ) )  Examiner: M. Graham
Filed: April 10, 1995	) )
For: THERMAL BLANKET	) )

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

transmitted to: Commissioner of Patents and Trademarks. Washington, D.C. 20231, on the date below:

10/12/95 Tensuco A. Mas

CERTIFICATE OF FACSIMILE TRANSMISSION 37 C.F.R. 1.8 I hereby certify that this correspondence is being facsimile

Dear Sir:

#### REQUEST FOR RECONSIDERATION

In response to the Final Action dated September 14, 1995 in this application, the Examiner is respectfully requested to reconsider and withdraw the Final Action (Paper 3).

The applicant submitted a Preliminary Amendment by first class mail certificate dated July 7, 1995. The applicant received a postcard stamped by the Patent Office mail room acknowledging receipt of the Preliminary Amendment on July 10, 1995. Copies of the Preliminary Amendment and stamped receipt are enclosed.

By the Preliminary Amendment, the applicant confirmed cancellation of Claims 4-7 and 11-25 made in the transmittal of the application. The applicant further cancelled Claims 1-3 and 8-9. Claims 26-35 were added to the application.

The mailing date of the Final Action is September 14, 1995, more than two (2) months after receipt of the Preliminary Amendment by the Patent Office. Accordingly, the Preliminary Amendment, while having been received by the Patent Office, was manifestly not considered by the Examiner when the Final Action was prepared and issued.

Since the Preliminary Amendment was timely and preceded the Final Action, the Examiner is respectfully requested to reconsider and withdraw the Final Action and to issue an Official Action based on examination of the claims that are at issue in this application.

Respectfully submitted,

TERRANCE A. MEADOR Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 "B" Street, Suite 3100 San Diego, California 92101

Phone: 619/233-9004 Fax: 619/544-1246 The USPTO date stamp hereon will acknowledge receipt of:

PRELIMINARY AMENDMENT for "Thermal Blanket" (6 pages)

Applicant:

S.D. Augustine et al

Assignee:

Augustine Medical, Inc.

Serial No.: Filed:

08/419,719 April 10, 1995

Mailed:

July 7, 1995

Enclosed:

Copy of page 671 of Dictionary

TAM/cmr 1342-119

The USPTO date stamp hereon will acknowledge receipt of:

PRELIMINARY AMENDMENT for "Thermal Blanket" (6 pages)

Applicant:

S.D. Augustine et al

Assignee:

Augustine Medical, Inc 08/419,719

Serial No.: Filed:

April 10, 1995

Mailed:

July 7, 1995

Enclosed:

Copy of page 671 of

RECEIVED

TAM/cmr 1342-119

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∆UG 14 1995

#### "PATENT"

Group No.: 3311

Examiner: Unknown

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

SCOTT D. AUGUSTINE

Serial No.: 08/419,719

Filed: April 10, 1995

For: THERMAL BLANKET

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

Dear Sir:

CERTIFICATE OF MAILING

37 C.F.R. 1.8 I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on the date below:

### PRELIMINARY AMENDMENT

Prior to the first examination, please amend the above-identified patent application as follows:

#### IN THE ABSTRACT

Please cancel the recitation of the Abstract and substitute the following therefor:

-- A thermal blanket includes an inflatable covering with a head end, a foot end, two edges, and an undersurface. The covering includes a plurality of inflatable chambers that are inflated when a thermal-

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controlled inflating medium is introduced into the thermal blanket through an inlet at the foot end. When inflated, the thermal blanket self-erects into a structure and provides a bath of thermally-controlled inflating medium to the interior of the erected structure through an aperture array on the undersurface of the inflatable covering. The thermal blanket is constructed for substantially longitudinal disposition over a portion of a patient's body extending from the pelvic area to the feet of the patient's body. Provision may be made for securing the inflatable covering to the patient's body at the head end. Provision may further be made for an uninflatable foot drape at the foot end.—

#### IN THE DESCRIPTION

Page 9, line 26, please change "20" to --10--.

Page 20, line 2, please change "heater" to --connecting--;

line 3, please change each occurrence of "tube" to -hose--; and

line 18, please change "heater tube" to --connecting

line 18, please change "heater tube" to --connecting hose--.

#### IN THE CLAIMS

The cancellation of Claims 4-7 and 11-25 in the transmittal of this application on April 10, 1995 is confirmed. Please cancel Claims 1-3 and 8-9. Please add the following claims:

26. (Added) An inflatable thermal blanket for covering and bathing a portion of a patient's body with thermally-controlled air,

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#### comprising:

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a flexible base sheet having a first end forming a first end of the thermal blanket, a second end forming a second end of the thermal blanket, two edges forming respective edges of the thermal blanket, and an undersurface forming an undersurface of the thermal blanket;

the first end, the second end, and respective edges of the base sheet forming a periphery of the thermal blanket;

the base sheet including a first layer of flexible material and a second layer of plastic material co-extensive with, and laminated to, the first layer of flexible material;

an overlaying flexible material sheet attached to the layer of plastic material by a plurality of seals to form the base sheet and the overlaying sheet into an inflatable covering which has a plurality of interconnected inflatable chambers;

said inflatable chambers in said covering for substantially longitudinal disposition over a portion of a patient's body extending substantially from the pelvic area of said patient's body to the feet of said patient's body;

an inflating inlet for admitting thermally controlled air into the inflatable chambers to inflate the covering;

a plurality of apertures opening through the base sheet into the chambers for exhausting thermally controlled air from the inflatable chambers through the base sheet in response to inflation and erection of the inflatable covering; and

a seal between the overlaying material sheet and the base sheet around the periphery.

27. (Added) The inflatable thermal blanket of Claim 26,

further including a non-inflatable foot extension formed in the inflatable covering at the second end for enclosing and warming a patient's feet in response to inflation of the inflatable covering.

- (Added) The inflatable thermal blanket of Claim 27, wherein the non-inflatable foot extension comprises the non-inflatable extension of the inflatable covering beyond the second end.
- (Added) The inflatable thermal blanket of Claim 27, wherein the non-inflatable foot extension includes an extension of the base sheet beyond the second end.
- (Added) The inflatable thermal blanket of Claim 27, wherein the plurality of seals are discontinuous elongate seams formed between the overlaying material sheet and the sheet of plastic material.
- (Added) The inflatable thermal blanket of Claim 30, 31. wherein the discontinuous elongate seams form the overlaying material sheet into the plurality of inflatable chambers, the plurality of inflatable chambers including parallel, communicating tubular chambers.
- (Added) The thermal blanket of Claim 30, wherein the 32. non-inflatable foot extension includes an extension of the base sheet beyond the second end.
- (Added) A thermal care system including the inflatable thermal blanket of Claim 27, and further including:

a heater/blower assembly for providing a source of heated air; and

a connecting hose coupled to the heater/blower assembly and to the inflating inlet for conducting heated air from the heated/blower assembly into the inflatable covering.

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34. (Added) A method of warming a person using a thermal blanket including an inflatable space form between a flexible base sheet and an overlaying material sheet attached to the base sheet by a peripheral seal around the periphery of the thermal blanket and a plurality of seals inside the periphery of the thermal blanket that form the base sheet and overlaying material sheet into an inflatable covering with a plurality of interconnected inflatable chambers, and apertures that open into the inflatable space through the flexible base sheet for exhausting air from the inflatable space, the method comprising the steps of:

disposing the thermal blanket to substantially longitudinally dispose the inflatable chambers over a portion of a patient's body extending substantially from the pelvic area of said patient's body to the feet of said patient's body;

inflating the thermal blanket with warmed air; and exhausting warmed air through the apertures in the flexible sheet.

35. (Added) The method of Claim 34, wherein the thermal blanket further includes a non-inflatable section formed in a portion of the periphery of the thermal blanket, the method further comprising the steps of:

the non-inflatable section forming a non-inflatable foot drape in the thermal blanket during the inflating step; and using the non-inflatable foot drape, trapping and retaining the heat under the thermal blanket during the exhausting step.

#### Remarks

The applicants enclose a copy of page 671 of the Ninth New

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Collegiate Dictionary for reference respecting the term "laminated to" which is supported in the originally-filed application at page 11, line 29.

The applicants now await the first examination in this application.

Respectfully submitted,

TERRANCE. A. MEADOR Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 "B" Street, Suite 2770 San Diego, California 92101

Phone: 619/233-9004 Fax: 619/544-1246

The ment (12-ment) of (MF & L: MF lamenter, fr. L. lamentari, fr. lamentum, n., lament; skin to ON lame toon, L. latture to bark. Ck. leves nonsensely if [15e]: to mourn about await, or it; to express sorrow or mourning for other demonstratively: MOURN 2: to regret strongly syrape before the strongly syrape crying out in grid: WAILING 2: DIRGE ELECTIVES.

3. COMPLAINT

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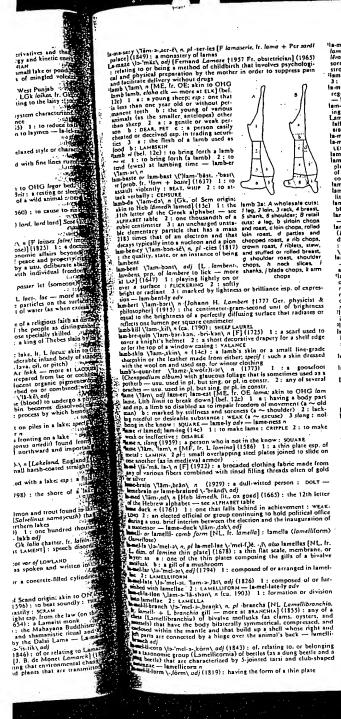
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Lamenta-tion \Jam-an-ti-shann, n (146): an act or instance of lamenta-tion \Jam-an-ti-shann, n (146): an act or instance of lamenta-ting \Jam-an-ti-shann, n (146): an act or instance of lamenta-ting \Jam-an-ti-shann, n (146): an act or instance of lamenta-ting \Jam-an-ti-shann, n (146): an act or instance of lamenta-ting \Jam-an-ti-shann, n (146): an act or instance of lamenta-tile \Jam-an-ti-shann, and Christian Scripture — see sitt table \Jam-an-ti-shann, and \Jam-an-ti-shann, and \Jam-an-ti-shann, and \Jam-an-ti-shann, and \Jam-an-ti-shann, \Jam-an-ti-shannn, \Jam-an-ti-shannn, \Jam-an-ti-shannn, \Jam-an-ti-shannn, \Jam-an-ti-shannn, \Jam-an-ti-shan

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This is a communication from the exal COMMISSIONER OF PATENTS AND	niner in charge of TRADEMARKS	your application.	·	09/14/95
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		onsive to communication filed on	4/10/97 🚎	This action is made final:
This application has been examin	ed Lef Hespi	onsive to communication filed on		y are
A shortened statutory period for respo Failure to respond within the period fo	nse to this action is r response will cau		days from days from doned. 35 U.S.C. 133	the date of this letter.
Part 1 THE FOLLOWING ATTACHM	MENT(S) ARE PAR	RT OF THIS ACTION:		
V	15	1-892 2. TN	otice of Drafteman's Pater	nt Drawing Review, PTO-948.
1. Notice of References Cited	-		otice of Informal Patent A	
3. Notice of Art Cited by Appl			P10 102	pphoanen, i i o i o a
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Part II SUMMARY OF ACTION		· -		•
· Carrier Company	1-7 ×	)_[])		
1. U Ciaims		10		are pending in the application.
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Of the above, claims		<u> </u>	are w	ithdrawn from consideration.
				nave been cancelled.
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5 Claims				are objected to.
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7 This application has been file	d with informal dra	wings under 37 C.F.R. 1.85 which a	re acceptable for examina	ation purposes.
7. This approaches has been me			•	
8.  -Formal drawings are required	in response to this	Office action.		
9. The corrected or substitute dr	awings have been		Under 37 C.F	
are acceptable; not acc	eptable (see expla	nation or Notice of Draftsman's Pat	tent Drawing Review, PTC	D-948).
		d drawings, filed on	has (have) been L	approved by the
examiner: disapproved by	the examiner (se	e explanation).		
14 The proposed drawing correct	tion filed	has been I ann	roved: I disapproved (s	ee explanation).

**EXAMINER'S ACTION** 

12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received

13. Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

\_\_\_\_ ; filed on \_\_

14. Dother

☐ been filed in parent application, serial no.



#### J DEPARTMENT OF COMMERCE Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

APPLICATION NUMBER FILING DATE FIRST NAMED APPLICANT ATTY, DOCKET NO /TITLE

DATE MAILED:

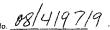
# NOTICE OF INFORMAL APPLICATION

(Attachment to Office Action)

This application does not conform with the rules governing applications for the reason(s) checked below. The period within which to correct these requirements and avoid abandonment is set in the accompanying Office action. A. A new oath or declaration, identifying this application by the application number and filing date is required. The oath or declaration does not comply with 37 CFR 1.63 in that it: 1. 
does not identify the city and state or foreign country of residence of each inventor. 2. \( \square\$ does not identify the citizenship of each inventor. 3. \( \square\$ does not state whether the inventor is a sole or joint inventor. 4. \( \square\$ does not state that the person making the oath or declaration: a. \( \square\) has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration. b. 🗆 believes the named inventor or inventors to be the original and the first inventor or inventors of the subject matter which is claimed and for which a patent is sought. c. 🗆 acknowledges the duty to disclose information which is material to patentability as defined in 37 CFR 1.56. 5. \( \square\) does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application serial number, country, day, month, and year of does not state that the person making the oath or declaration acknowledges the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and filing date of the continuation-in-part application which discloses and claims subject matter in addition to that disclosed in the prior application (37 CFR 1.63(d)). 7. \( \square\) does not include the date of execution. 8. \(\subseteq\) does not use permanent ink, or its equivalent in quality, as required under 37 CFR 1.52(a). 9. ☐ contains non-initialed alterations (See 37 CFR 1.52(c)). 10. Other: B. Applicant is required to provide: 1. 

A statement signed by applicant giving his or her complete name. A full name must include at least one given name without abbreviation as required by (37 CFR 1.41(a)). 2. Proof of authority of the legal representative under 37 CFR 1.44. 3. An abstract in compliance with 37 CFR 1.72(b). 4. A statement signed by applicant giving his or her complete post office address (37 CFR 1.33(a)). A copy of the specification written, typed, or printed in permanent ink, or its equivalent in quality as required by 37 CFR 1.52(a).

PART 3-COPY TO BE RETURNED WITH RESPONSE



# NOTICE OF DRAFTSPERSON'S PATENT DRAWING REVIEW

PTO Draftpersons review all originally filed drawings regardless of whether they are designated as formal or informal. Additionally, patent Examiners will review the drawings for compliance with the regulations. Direct telephone inquiries concerning this review to the Drawing Review Branch, 703-305-8404.

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The drawings filed (insert date). 41/0/95 and objected to by the Draftsperson under VCCPE (A4 or 1.15). B	View and enlarged view not labled separatly or properly.  Ge(s)  Sectional views. 37 CPR + 84 (b) 3.  Date on not collected for sectional portions of an object.  Gg(s).
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Fig(s) Individuals waveform not identified with a separate letter designation adjacent to the vertical axis. Fig(s) 4. TYPE OF PAPER, 37 CFR 1.84(c)	11. SHADING, 37 CFR 1.84(m) Solid black shading areas not permitted. Fig(s) Shade lines, pale, rough and blurred. Fig(s)
Paper not flexible, strong, white, smooth, nonshiny, and durable, Sheet(s).  Erasures, alterations, overwritings, interfineations or next, even flexible and folds, energy mortains, some folds at explicit. Fig.(3).	<ol> <li>NUMBERS, LETTERS, &amp; REFERENCE CHARACTERS. 37 CFR 1.84(p)</li> <li>Monthers and reference characters not plain and legible. 37 CFR</li> </ol>
Mylar, veilum papur is sait er epiable (toe (hin), Ugos)  5. SIZE (il) PAPUR - 17 CPR (-8 (1)) Acceptable (i) : 21.6 cm, by 35.6 cm, (8 92 by 14 inches)  21.6 cm, by 35.1 cm, (8 02 by 13 inches)	Using the Figure 1. Pages 1. Pages 1. Pages 1. Pages 1. Pages 2. Pages 1. P
71.6 cm, by 27.9 cm, (2 1/2 by 14 bedies) 21.0 cm, by 29.7 cm, (2108 size A4)  f. All drawing sheets not the same size. Sheet(s)  Orawing sheet not an acceptable size. Sheet(s)	<ul> <li>Fig.(a)</li> <li>Mumbers, lettim, and reference characters do not mensure at least 32 cm. (1% such) in height. 37 CFR(ρ)(3)</li> <li>Og(c)</li> </ul>
6. MARGINS, 37 CFR 1.84(g): Acceptable margins  Paper size  2.1 6 cm, X 15 6 cm, 24 6 cm, X 37,7 cm, 3 6 cm, X 27,9 cm, 24 9 cm, 3 9,7 cm, (3 80.7 X 14 inches) (3 80.7 X 14 inches) (3 80.7 X 14 inches) (3 80.7 X 14 inches) (3 80.7 X 14 inches) (3 80.7 X 14 inches) (3 80.7 X 15 cm, (27)	12 LEAD LANES, "7 CPR LBM(q)  Lead lines cross cach other "Fig(s)  Lead lines missing, "Fig(s)  13 NDARF-RING (**) NDFF/TS (**) DPAWINGS, "7 CPR + 84(t)  Shoots not membered consecutively, and in Arabic nonorals, originating with rands," i. Shoots  15 NDAMER OF VIEWS, "7 CPR LBM(q)  Misws and membered consecutively, and in Arabic nonorals,
Mangins do not conform to chan an syr. Sheete)  Top (T) Left (L.) Right (R) Bottom (B)	beginning with number 1. Fig(s)  View maybers put preceded by the aldneviation Fig and 20  Fig(s) 77
VIEWS, 37 CER 1.84(h)     REMINDER: Specification may require revision to correspond to drawing changes.	16. CORRECTIONS, 37 CFR 1.84(w) Corrections not reade from prior PTO-948. Pig(s)
All views not grouped together. Fig(s)  Views connected by projection lines or lead lines  Fig(s)  Partial views. 37 CFR 1.34(h) 2	DESIGN DRAWING, 37 CFR 1.152     Surface shading shown not appropriate. Fig(s)     Solid black shading not used for color contrast. Fig(s)
_ COMMENTS:	
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Serial Number: 08/419,719

Art Unit: 3304

Claims 1-3 and 8-10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Base claims 1 and 8 both recite that the blanket is "sized to extend" across a certain portion of a patients body.

Obviously this is a dimension which would vary from patient to patient thus leaving the limits on the claims unclear.

The following is a quotation of 35 U.S.C.  $\S$  103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 8 and 9 are rejected under 35 U.S.C. § 103 as being unpatentable over Kliesrath in view of Augustine for the reasons set forth in the 11/5/91 rejection of the parent application.

Claim 10 is rejected under 35 U.S.C. § 103 as being unpatentable over the art as applied to claim 8 above, and

Serial Number: 08/419,719

Art Unit: 3304

further in view of Sandhaus for the reasons set forth in the 11/5/91 rejection of the parent application.

Claims 1 and 8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 5,324,320. Although the conflicting claims are not identical, they are not patentably distinct from each other because sizing the '320 blanket to fit various areas of the body would have been obvious to one of ordinary skill in the art.

Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 5,324,320 in view of Kliesrath for the reasons set forth in the 11/5/91 rejection of the parent application.

Claims 3 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 5,324,320 in view of Sandhaus for the reasons set forth in the 11/5/91 rejection of the parent application.

Claim 9 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 5,324,320 in view of Greene for the reasons set forth in the 11/5/91 rejection of the parent application.

Serial Number: 08/419,719

Art Unit: 3304

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

This is a continuation of applicant's earlier application S.N. 07/638,748. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds or art of record in the next Office action if they had been entered in the earlier application.

Accordingly, THIS ACTION IS MADE FINAL even though it is a first action in this case. See M.P.E.P. § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Serial Number: 08/419,719 -5-

Art Unit: 3304

Any inquiry concerning this communication should be directed to Mark S. Graham at telephone number (703) 308-1355.

MSG September 8, 1995

> MARK S. GRAHAM PRIMARY EXAMINER PRIMARY 03300

The USPTO date stamp hereon will acknowledge receipt of:

INFORMATION DISCLOSURE STATEMENT for "Thermal Blanket" (2 pgs)

Applicant:

Scott D. Agusutine et al

Assignee:

Augustine Medical, Inc.

Serial No.:

08/419,719

Filed:

April 10, 1995

Mailed:

Enclosed:

PTO 1449 and listed Williams Reference Copies of Information Disclosure Statements for 07/550,757, 07/227,189, and 07/104,682

Change of Address Notification

TAM/cmr 1342-119

The USPTO date stamp hereon will acknowledge receipt of:

INFORMATION DISCLOSURE STATEMENT for "Thermal Blanket" (2 pgs)

Applicant:

Scott D. Agusutine et al

Assignee:

Augustine Medical, Inc. 82

Serial No.:

08/419,719 April 10, 1995

Filed:

Mailed:

August \_\_ , 1995

Enclosed:

PTO 1449 and listed Williams Reference Copies of Information Disclosure Statements

for 07/550,757, 07/227,189, and 07/104,682

Change of Address Notification

TAM/cmr 1342-119 (84)

#### "PATENT"

Group No.: 3311

Examiner: Unknown

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

S.D. Augustine et al

Serial No.: 08/419,719

Filed: April 10, 1995

For: THERMAL BLANKET

Honorable Commissioner of

Washington, D.C. 20231

Patents and Trademarks

CERTIFICATE OF MAILING

37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on the date below:

01810 Ton and A Ared

Dear Sir:

# INFORMATION DISCLOSURE STATEMENT

In satisfaction of their duty of candor and fair dealing, the applicants hereby cite the documents listed on the accompanying PTO-1449 forms (copies enclosed) which were submitted in the parent application (07/550,757, 07/227,189, and 07/104,682) of the above-identified patent application under the provisions of 37 CFR, Sections 1.56, 1.97, and 1.98. A form PTO 1449 for this application is also

CLAREICLIENTVI34Z-119.IDS

enclosed together with a legible copy of the reference which it lists (U.S. Patent No. 2,512,559).

The filing of this Information Disclosure Statement should not be construed to mean that a search was conducted or that no other material information, as defined by 37 CFR 1.56, exists. The Examiner is respectfully requested to make of record what he deems relevant to the examination of this application.

Respectfully submitted,

TERRANCE A. MEADOR Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 "B" Street, Suite 3100 San Diego, California 92101

Phone: 619/233-9004 Fax: 619/544-1246 ırm PTO-1449

# INFORMATION DISCLOSURE CITATION

Docket No. 1342-119	Application No.	08/419,719
Applicant: S.D. Augustine et a	ı	
Filing Date: 411010E	Consum Ant Unit	2211

	IN AN APPLICA	ATION		Applicant: S.U. Augustine et al									
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(Form PTO-1449 [6-4])

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: SCOTT D. AUGUSTINE ET AL

Serial No: 227,189

Group Art Unit: 334

Filed: August 2, 1988

For: THERMAL BLANKET

Examiner: Unknown

# INFORMATION DISCLOSURE STATEMENT

In satisfaction of the duty of disclosure, the applicants hereby submit a copy of a Search Report

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TERRANCE A. MEADOR (Applicant, A., . . . . .

returned in European Patent Application No. EPO 88309191.0. This EPO application claims priority of the parent of this application, U.S. Patent Application Serial No. 07/104,682, filed October 5, 1987, for "THERMAL BLANKET", which is now abandoned, and the identified application.

The Search Report indicates that all of the references found by the Examiner form the technological background of the invention. In addition, U.S. Patent No. 4,572,188 is designated as being cited in the application.

Also disclosed are the three references returned with the European Search Report. The first reference, U.S. Patent 4,572,188 has already been cited and discussed in the preliminary amendment to this application, submitted October 10, 1988.

The German Patent DE3308553 was provided without translation; the applicants do not have an English translation of this patent. From the figures, the patent appears to cover a vest with a series of tubular chambers, which might be inflated when the vest is in use.

U.S. Patent 3,714,947 describes a baby blanket designed to control hypothermia and consisting of an envelope having an upper portion with a provision for circulating a temperature-controlled fluid through the

blanket.

The Examiner is requested to consider these references and to make of record those deemed to be material to examination of this application.

Respectfully submitted,

Tenance A. Meador

Attorney for Applicant(s) Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR 110 West "C" Street, Suite 1202 San Diego, California 92101

Telephone: (619) 233-9004

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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

SCOTT D. AUGUSTINE ET AL

Serial No: 07/104,682

Filed: August 2, 1988

For: THERMAL BLANKET

Examiner: Unknown

INFORMATION DISCLOSURE STATEMENT

In satisfaction of the applicants' duty of candor and fair dealing, disclosure is made of issued United States Patents relating to body warming.

I hereby cartify that this correspondence Is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trad. The Whitedon, D.C. 20231 on April 25, 1989

TERRANCE A. MEADOR

(Applicant, Assignee, Registered Representative)

Lenance A. Meadon

(Signature)

April 25, 1989

(Date of Signature)

The disclosed patents represent the result of a patentability search conducted on an invention made by the applicants for which a patent application has not yet been filed.

The information disclosed hereby carries no implication that other information, more material to the invention described and claimed in the identified application, does not exist.

• The Examiner is requested to review these patents and to make of record those which are considered to be material to examination of this application.

Respectfully submitted,

TERRANCE A. MEADOR

Attorney for Applicant(s) Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR 110 West "C" Street, Suite 1202 San Diego, California 92101

Telephone: (619) 233-9004

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EXAMINER

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

SCOTT D. AUGUSTINE

Serial No: 07/550,757

Filed: July 10, 1990

For: THERMAL BLANKET

Examiner:

M. Graham

Commissioner of Patents and Trademarks Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

In satisfaction of the duty of candor and fair dealing, the applicants hereby disclose the publication listed on the attached Form 1449.

TERRANCE A. MEADOR

auch /

(Signature) August 23, 1991

(Date of Signature)

The listed reference is a copy of European Patent
Application 88309191.0 which was published on May 12,
1989. This European application corresponds to, and claims
priority from, the applications identified as parents of
the application identified in the caption of this paper.

The Examiner is requested to review the reference and, if deemed material to the examination of this application, to make it of record in the file.

Respectfully submitted,

TERRANCE A. MEADOR Attorney for Applicant Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 "B" Street, Suite 2770 San Diego, California 92101

Telephone: (619) 233-9004

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(Form PTO-1449 [6-4])

# "PATENT"

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

S.D. Augustine et al

Group No.: 3311

Serial No.: 08/419,719

Examiner: Unknown

Filed: April 10, 1995

For: THERMAL BLANKET

CERTIFICATE OF MAILING

37 C.F.R. 1.8
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner of Patents and Trademarks. Washington, D.C. 20231, on the date below:

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

Dear Sir:

#### CHANGE OF ADDRESS

This is to notify the Office that all correspondence in the

subject matter should be addressed to:

Terrance A. Meador BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 "B" Street, Suite 3100 San Diego, California 92101

\clare\FORMS\address.chg

Please direct all telephone calls and facsimile transmissions to:

Terrance A. Meador

Phone:

619/233-9004

Fax:

619/544-1246

Respectfully,

Terrance A. Meador

Registration No.: 30,298

BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 "B" Street, Suite 3100 San Diego, California 92101 The USPTO date stamp hereon will acknowledge receipt of:

PRELIMINARY AMENDMENT for "Thermal Blanket" (6 pages)

Applicant:

S.D. Augustine et al Augustine Medical, Inc.

Assignee: Serial No.: 08/419,719 April 10, 1995

Filed:

Mailed:

July 7, 1995

Enclosed:

Copy of page 671 of Dictionary

TAM/cmr 1342-119

The USPTO date stamp hereon will acknowledge receipt of:

PRELIMINARY AMENDMENT for "Thermal Blanket" (6 pages)

Applicant:

S.D. Augustine et al Augustine Medical, Inc

Assignee: Serial No.: Filed:

08/419,719 April 10, 1995

Mailed:

July 7, 1995

Enclosed:

Copy of page 671 of

BECEIVED

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TAM/cmr 1342-119

#### "PATENT"

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

SCOTT D. AUGUSTINE

Group No.: 3311

Serial No.: 08/419,719

Examiner: Unknown

Filed: April 10, 1995

For: THERMAL BLANKET

Honorable Commissioner of

Washington, D.C. 20231

Patents and Trademarks

CERTIFICATE OF MAILING

37 C.F.R. 1.8 I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on the date below:

Dear Sir:

#### PRELIMINARY AMENDMENT

Prior to the first examination, please amend the above-identified patent application as follows:

# IN THE ABSTRACT

Please cancel the recitation of the Abstract and substitute the following therefor:

-- A thermal blanket includes an inflatable covering with a head end, a foot end, two edges, and an undersurface. The covering includes a plurality of inflatable chambers that are inflated when a thermal-

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controlled inflating medium is introduced into the thermal blanket through an inlet at the foot end. When inflated, the thermal blanket self-erects into a structure and provides a bath of thermally-controlled inflating medium to the interior of the erected structure through an aperture array on the undersurface of the inflatable covering. The thermal blanket is constructed for substantially longitudinal disposition over a portion of a patient's body extending from the pelvic area to the feet of the patient's body. Provision may be made for securing the inflatable covering to the patient's body at the head end. Provision may further be made for an uninflatable foot drape at the foot end.--

#### IN THE DESCRIPTION

Page 9, line 26, please change "20" to --10--.

Page 20, line 2, please change "heater" to --connecting--;

line 3, please change each occurrence of "tube" to --hose--; and

line 18, please change "heater tube" to --connecting hose--.

#### IN THE CLAIMS

The cancellation of Claims 4-7 and 11-25 in the transmittal of this application on April 10, 1995 is confirmed. Please cancel Claims 1-3 and 8-9. Please add the following claims:

26. (Added) An inflatable thermal blanket for covering and bathing a portion of a patient's body with thermally-controlled air,

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2

3	comprising:
4	a flexible base sheet having a first end forming a first end
5	of the thermal blanket, a second end forming a second end of
6	the thermal blanket, two edges forming respective edges of the
7	thermal blanket, and an undersurface forming an undersurface
8	of the thermal blanket;
9	the first end, the second end, and respective edges of th
0	base sheet forming a periphery of the thermal blanket;
1	the base sheet including a first layer of flexible material
2	and a second layer of plastic material co-extensive with, and
3	laminated to, the first layer of flexible material;
.4	an overlaying flexible material sheet attached to the layer
15	of plastic material by a plurality of seals to form the base sheet
16	and the overlaying sheet into an inflatable covering which has a
17	plurality of interconnected inflatable chambers;
18	said inflatable chambers in said covering for substantially
19	longitudinal disposition over a portion of a patient's body
20	extending substantially from the pelvic area of said patient's
21	body to the feet of said patient's body;
22	an inflating inlet for admitting thermally controlled air into
23	the inflatable chambers to inflate the covering;
24	a plurality of apertures opening through the base sheet
25	into the chambers for exhausting thermally controlled air from
26	the inflatable chambers through the base sheet in response to
27	inflation and erection of the inflatable covering; and
28	a seal between the overlaying material sheet and the bas
29	sheet around the periphery.

27. (Added) The inflatable thermal blanket of Claim 26,

2	further including a non-inflatable foot extension formed in the							
3	inflatable covering at the second end for enclosing and warming a							
4	patient's feet in response to inflation of the inflatable covering.							
l	28. (Added) The inflatable thermal blanket of Claim 27,							
2	wherein the non-inflatable foot extension comprises the non-inflatable							
3	extension of the inflatable covering beyond the second end.							
I	29. (Added) The inflatable thermal blanket of Claim 27,							
2	wherein the non-inflatable foot extension includes an extension of the							
3	base sheet beyond the second end.							
1	30. (Added) The inflatable thermal blanket of Claim 27,							
2	wherein the plurality of seals are discontinuous elongate seams							
3	formed between the overlaying material sheet and the sheet of plastic							
1	material.							
	31. (Added) The inflatable thermal blanket of Claim 30,							
2	wherein the discontinuous elongate seams form the overlaying							
3	material sheet into the plurality of inflatable chambers, the plurality of							
4	inflatable chambers including parallel, communicating tubular							
5	chambers.							
t	32. (Added) The thermal blanket of Claim 30, wherein the							
2	non-inflatable foot extension includes an extension of the base sheet							
3	beyond the second end.							
	33. (Added) A thermal care system including the inflatable							
2	thermal blanket of Claim 27, and further including:							
3	a heater/blower assembly for providing a source of							
ļ	heated air; and							
;	a connecting hose coupled to the heater/blower assembly							
j	and to the inflating inlet for conducting heated air from the							
1	heated/blower assembly into the inflatable covering.							

1	34. (Added) A method of warming a person using a thermal
2	blanket including an inflatable space form between a flexible base
3	sheet and an overlaying material sheet attached to the base sheet by
4	peripheral seal around the periphery of the thermal blanket and a
5	plurality of seals inside the periphery of the thermal blanket that form
6	the base sheet and overlaying material sheet into an inflatable
7	covering with a plurality of interconnected inflatable chambers, and
8	apertures that open into the inflatable space through the flexible base
9	sheet for exhausting air from the inflatable space, the method
0	comprising the steps of:
1	disposing the thermal blanket to substantially
12	longitudinally dispose the inflatable chambers over a portion of
13	a patient's body extending substantially from the pelvic area of
14	said patient's body to the feet of said patient's body;

inflating the thermal blanket with warmed air; and exhausting warmed air through the apertures in the flexible sheet.

35. (Added) The method of Claim 34, wherein the thermal blanket further includes a non-inflatable section formed in a portion of the periphery of the thermal blanket, the method further comprising the steps of:

the non-inflatable section forming a non-inflatable foot drape in the thermal blanket during the inflating step; and using the non-inflatable foot drape, trapping and retaining the heat under the thermal blanket during the exhausting step.

#### Remarks

The applicants enclose a copy of page 671 of the Ninth New

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Collegiate Dictionary for reference respecting the term "laminated to" which is supported in the originally-filed application at page 11, line 29.

The applicants now await the first examination in this application.

Respectfully submitted,

TERRANCE. A. MEADOR Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 "B" Street, Suite 2770 San Diego, California 92101

Phone: 619/233-9004 Fax: 619/544-1246

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'la-ment \la-'ment\ vb [MF & L; MF lamenter, Ir, L lamentari, Ir, L lamentari, Ir, L lamentari, Ir, lamentum, n., lament; akin to ON låmr loon. L latrare to batk, Ck lfros nonsnatos | vi (15c) to mourn aloud; wait, ~ vi 1; to express sorrow or mourning for often demonstratively: MOURN 2: to regret strongly 15m see DEFLORE sorrow or mourning for often demonstratively: MOURN 2: 10 regret strongly Syrisee DEPLORE "lament n (1591) 1: a crying out in grief: WAILING 2: DIRGE ELEGY

1. CONTAINE 1. CONTAINE 1. CONTAINE 1. In that is to be regretted or lamented: DEPLORABLE 2: expressing grief: MOURNFUL - lamentable bleeness n - lamentably / bild / dv lamentablo lamentable results n - lamentably | bild | dv lamentablo | Jamentablo | lamentablo entable Vlam-2n-12-bal, la-ment-2-\ add (13c) 1: that is to be regreited or lamented: Dept.08-81E 2: expressing grief: MOURNFUL—lamentableness n—lamentably \.bid\(\frac{1}{2}\) bid\(\frac{1}{2}\) bid\

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UNITED STATES ... MENT OF COMMERCE Patent and Trademark Office ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'O	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
08/419,719	04/10/95	3311	\$365.00	1342-119	5	6	2

TERRANCE A MEADOR BAKER MAXHAM JESTER & MEADOR SYMPHONY TOWERS 750 B STREET SUITE 2770 SAN DIEGO CA 92101

Receipt is acknowledged of this patent application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Application Processing Division's Customer Correction Branch within 10 days of receipt. Please provide a copy of the Filing Receipt with the changes noted thereon.

Applicant(s)

SCOTT D. AUGUSTINE, BLOOMINGTON, MN; RANDALL C. ARNOLD, MAPLEWOOD, MN.

CONTINUING DATA AS CLAIMED BY APPLICANT-

THIS APPLN IS A CON OF 07/638,748 01/08/91 PAT 5,405,371 WHICH IS A CIP OF 07/550,757 07/10/90 WHICH IS A CIP OF 07/227,189 08/02/88 WHICH IS A CIP OF 07/104,682 10/05/87 ABN

FOREIGN FILING LICENSE GRANTED 05/01/95 TITLE THERMAL BLANKET

\* SMALL ENTITY \*

PRELIMINARY CLASS: 607

(see reverse)

000 U.S.P.T.O. UCH DATE DESCRIPTION 04/10/95 1342-119 CONTINUATION PA 729

CASE · 1342119

12189 AMOUNT 365.00

04/10/95 TOTAL PAID 365.00 8776124030 US SEE REVERSE FOR SERVICE GUARANTEE INSURANCE COVERAGE AND CLAIMS. ORIGIN THANK YOU FOR CHOOSING EXPRESS MAIL SERVICE. Initials of Receiving Clerk ACCEPTANCE | International Country Code Next Day Delivery Of Second Day Deliver By 12 Noon Or By 3:00 P.M. Military 2nd Day Express Mail Corporate Account No. Walver of Signature and Indemnity (Domestic Only) FROM: PAKE Telephone Number: STANDFWAEL TRADEWAEL TAd/nur 1305-119 (1.60 Continuation Continuation Patent Application Enc (OCCUPATION CONTRACTOR OF THE The USPTO date stamp hereon will acknowldge receipt of:

The USPTO date stamp hereon will acknowldge receipt of:

. Blanket"

1.60 CONTINUATION PATENT APPLICATION for "Thermal Blanket"

Applicant: Assignee:

Scott D. Augustine et al Augustine Medical, Inc.

24030US

·y)

Mailed:

EXPRESS MAIL April 10, 1995 TB

Enclosed:

Transmittal (in duplicate)

Specification (23 pgs)

Claims (9 pgs) Abstract (2 pgs)

Drawings (5 shepts)

Small Entity Systement (copy) Declaration/Power of Attorney (copy)

Express Mail Certification

Check for \$365

TAM/cmr 1342-119

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Date of Deposit April 10, 1995

I hereby certify that this paper or fee Is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

CLARE M. ROBERTS

· (Signature)

#### REQUEST FORM FOR FILING A PATENT APPLICATION UNDER 37 CFR 1.60

DATE: April 10, 1995

DOCKET NUMBER	ANTICIPATED CLASSIFICATION OF THIS APPLICATION		PRIOR APPLICATION EXAMIN	ER ART UNIT
1342-119	CLASS:	SUBCLASS:	M. GRAHAM	3304

Address to:

Commissioner of Patents and Trademarks Washington, D.C. 20231

This is a Request for filing a continuation application under 37 CFR 1.60, of pending application Number 07/638,748, filed January 18, 1991 entitled "THERMAL RLANKET"

Enclosed is a copy of the latest inventor-signed prior application, including a copy of the oath or declaration showing the original signature or an indication it was signed. I hereby verify that the papers are a true copy of the latest signed prior application number 07/638,748, and further that all statements made herein of my own knowledge are true; and further that these statements were made with the knowledge that willful false statements and the like are made punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issuing thereon.

	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
CLAIMS	TOTAL CLAIMS	6 - 20 -		x \$ 22.00 -	\$
	INDEPENDENT CLAIMS	2 - 3 -		x \$ 76.00 -	\$
	MULTIPLE DEPENDENT CLAI	\$			
				BASIC FEE	\$ 730.00
			Total of ab	ove Calculations -	\$ 365.00
	Reduction by 50% for filing	Small Entity (Note 37 C	FR 1.9, 1.27, 1.28).		
				TOTAL =	\$ 365.00

2.	X A vei	rified statement to	ı establish sm	all entit	y status uni	der 37	CFR	1.9 an	d 1.2	7						
		is enclosed.														
	<u>X</u>	was filed in prio	r application i	number	07/638,748	and s	uch s	tatus is	still	proper	and	desired	(37 C	FR 1	1.28(a)).	

- 3. X The Commissioner is hereby authorized to charge any fees which may be required under 37 CFR 1.16 and 1.17, or credit any overpayment to Deposit Account No. <u>02-0460</u>. A duplicate copy of this sheet is enclosed.
- 4. X A check in the amount of \$365.00 is enclosed.
- 5. X Cancel in this application original claims 4-7, 11-25 of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)
- 6. X Amend the specification by inserting before the first line the sentence: "This application is a continuation of application number 07/638,748, filed January 8, 1991, (status: pending)."
- Transfer the drawings from the pending prior application to this application and abandon said prior application as of the filing date accorded this application. A duplicate copy of this sheet is enclosed for filing in the prior application. (May only be used if signed by person authorized by 37 CFR 1.138 and before payment of issue fee.)

8.		New	formal	drawings	are	enclosed.				
	12	.921					<b>IPage</b>	1	nf	2

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

TAM/PTO\1342-119.160

## (REQUEST FORM FOR FILING A PATENT APPLICATION UNDER 37 CFR 1.60, Page 2) DOCKET NO .: 1342-119 9. \_\_\_ Priority of foreign application number \_\_\_ \_\_ filed on \_ claimed under 35 U.S.C. 119. \_\_\_\_ The certified copy has been filed in prior application number \_\_\_\_\_\_\_ filed \_\_\_\_ 10. \_\_\_ A preliminary amendment is enclosed. 11. X The prior application is assigned of record to AUGUSTINE MEDICAL, INC. 12. \_\_\_\_ Also enclosed: 13. X The power of attorney in the prior application is to: Terrance A. Meador BAKER, MAXHAM, JESTER & MEADOR 110 West "C" Street, Suite 1202 San Diego, California 92101 a. X The power of attorney appears in the original papers in the prior application. Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed. c. X Address all future correspondence to: (May only be completed by applicant, or attorney or agent of record.) Terrance A. Meador BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 "B" Street, Suite 2770 San Diego, California 92101 Inventor(s) TERRANCE A. MEADOR (30,298) Assignee of complete interest Typed or printed name (& registration number if applicable) X Attorney or agent of record

(2.92)

(Page 2 of 2 )

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

TAM\PTO\1342-119.160

Filed under 37 CFR 1.34(a)

Registration number if acting under 37 CFR 1.34(a).

DATE: April 10, 1995

OOCKET NUMBER		IPATED CLASSIFICATION F THIS APPLICATION	PRIOR APPLICATION EXAMINER	ART UNIT
342-119	CLASS:	SUBCLASS:	M. GRAHAM	3304

dress to:

Commissioner of Patents and Trademarks Washington, D.C. 20231

is is a Request for filing a continuation application under 37 CFR 1.60, of pending application Number 07/638,748, filed January 18, 1991 entitled HERMAL BLANKET\*

closed is a copy of the latest inventor-signed prior application, including a copy of the oath or declaration showing the original signature or an indication was signed. I hereby verify that the papers are a true copy of the latest signed prior application number 07/638,748, and further that all statements ide herein of my own knowledge are true; and further that these statements were made with the knowledge that willful false statements and the like a made punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful statements may spardize the validity of the application or any patent issuing thereon.

	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
CLAIMS	TOTAL CLAIMS	6 - 20 -		x \$ 22.00 -	\$
	INDEPENDENT CLAIMS	2 · 3 -		x \$ 76.00 -	\$
	MULTIPLE DEPENDENT CLAIM	S (if applicable)		+ \$ 240.00 -	\$
				BASIC FEE	\$ 730.00
			Total of ab	ove Calculations -	\$ 365.00
	Reduction by 50% for filing a	Small Entity (Note 37 C	FR 1.9, 1.27, 1.28).		
				TOTAL =	\$ 365.00

X	A verified statement to establish small entity status under 37 CFR 1.9 and 1.27  is enclosed.  X was filed in prior application number 97/638,748 and such status is still proper and desired (37 CFR 1.28(a)).
_X_	The Commissioner is hereby authorized to charge any fees which may be required under 37 CFR 1.16 and 1.17, or credit any overpayment to Deposit Account No. <u>02-0460</u> . A duplicate copy of this sheet is enclosed.
X	A check in the amount of \$365.00 is enclosed.
<u>x</u>	Cancel in this application original claims 4-7, 11-25 of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)
X	Amend the specification by inserting before the first line the sentence: "This application is a <i>continuation</i> of application number 07/638,748, filed January 8, 1991, (status: pending)."
	Transfer the drawings from the pending prior application to this application and abandon said prior application as of the filing date accorded this application. A duplicate copy of this sheet is enclosed for filing in the prior application. (May only be used if signed by person authorized by 37 CFR 1.138 and before payment of issue fee.)
<u></u>	New formal drawings are enclosed.  92) {Page 1 of 2   Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

TAM\PTO\1342-119.160

# REQUEST FORM FOR FILING A PATENT APPLICATION UNDER 37 CFR 1.60, Page 2) DOCKET NO .: 1342-119 ). \_\_\_\_ Priority of foreign application number \_\_\_ claimed under 35 U.S.C. 119. \_\_\_\_ The certified copy has been filed in prior application number \_\_/\_\_\_\_\_ filed \_\_ 10. \_\_\_ A preliminary amendment is enclosed. 11. X The prior application is assigned of record to AUGUSTINE MEDICAL, INC. 12. \_\_\_ Also enclosed: 13. X The power of attorney in the prior application is to: Terrance A. Meador BAKER, MAXHAM, JESTER & MEADOR 110 West "C" Street, Suite 1202 San Diego, California 92101 a. $\underline{X}$ The power of attorney appears in the original papers in the prior application. b. Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed. c. X Address all future correspondence to: (May only be completed by applicant, or attorney or agent of record.) Terrance A. Meador BAKER, MAXHAM, JESTER & MEADOR Symphony Towers 750 "B" Street, Suite 2770 San Diego, California 92101 Inventor(s) TERRANCE A. MEADOR (30,298) Assignee of complete interest Typed or printed name (& registration number if applicable) X Attorney or agent of record Filed under 37 CFR 1.34(a) Registration number if acting under 37 CFR 1.34(a).

(2-92)

[Page 2 of 2]

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

TAM\PTO\1342-119.160

ant or Patentee: SCOTT D.	GUSTINE. ET AL.	t attorney's
or Patent No.: Unknown		Docket No.:0603
or Issued: Herewith "THERMAL BLANKET"	<del></del>	
VERIFTED SI SIMIUS (37 CFR	RIDEN (DECLARATION) CLAIMING . 1.9(f) and 1.27(c)) — SYML BY	SPAL ENTTY SINESS CONCERN
y declare that I an I the ower of the small business I an official of the small business	s cancern identified below: ess cancern exponenced bo act on beha	olf of the concern identified below:
WE OF CONCERN AUGUSTINE M DRESS OF CONCERN 10393 Wes	EDICAL, INC t 70th Street, Suite 100	Eden Prairie, MN 55344
i as defined in 13 CFR 121.3- i fees under section 41(a) and ses of the concern, includir sof this statement, (1) the vious fiscal year of the conce sais during each of the pay, ther when either, directly or i	-18, and reproduced in 37 CFR 1 d (b) of Title 35, United State on those of its affiliates, doe number of employees of the busi ern of the persons employed on a periods of the fiscal year.	o qualifies as a small business9(d), for purposes of paying is Code, in that the number of its not exceed 500 persons. For ness concern is the average over a full-time, part-time or tempol (2) concerns are affiliates of or has the power to control the rol both.
by declare that rights under one concern identified above with	h regard to the invention, enti	ed to and remain with the small tled <u>"THERMAL BLANKET"</u>
OTT D. AUGUSTINE and RAI  X) the specification filed her application serial no. patent no.	NDALL C. ARNOLD ewith, file	by inventor(s) described in
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#### THERMAL BLANKET

#### RELATED APPLICATIONS

This is a continuation-in-part of application serial no. 07,550,757, filed July 10, 1990, which is a continuation-in-part of application serial no. 07,227,189, filed August 2, 1988, which is a continuation-in-part of application serial no. 07,104,682, filed October 5, 1987.

### BACKGROUND OF THE INVENTION

This invention relates to thermal blankets used in a medical setting to deliver a bath of a thermally-controlled medium to a patient.

The thermal blanket prior art is best expressed in our prior U.S. Patent No. 4,572,188 entitled "AIRFLOW COVER FOR CONTROLLING BODY TEMPERATURE." In our prior patent, a self-erecting, inflatable airflow cover is inflated by the introduction into the cover of a thermally-controlled inflating medium, such as warmed air. When inflated, the cover self-erects about a patient, thereby creating an ambient environment about the patient, the thermal characteristics of which are determined by the temperature of the inflating medium. Holes on the underside of our prior art airflow cover exhaust the thermally-controlled, inflating medium from inside the cover to the interior of the erected structure. Our airflow cover is intended for treatment οf hypothermia, as might occur postoperatively.

Evaluation of our airflow cover bv practitioners has resulted in general approbation: opinion is that the airflow cover efficiently effectively accomplishes its purpose giving ο£ thermally-controlled bath. We have realized, however, that, while our prior art airflow cover achieves its objective, certain improvements to it are necessary in order to realize additional clinical objectives and to enjoy further advantages in its use.

#### SUMMARY OF THE INVENTION

We have improved the clinical usefulness of our self-erecting airflow cover by observing that controlling the contour of its inflatable portion at its head end to define a generally concave non-inflatable portion will permit a care giver to more easily observe a patent's head, face, neck and chest. Further, we have observed that limited venting of the thermally controlled inflating medium from the edges of the cover results in efficient, more uniform heating within the cover. We have also observed that it is good clinical practice to keep the area of the care site in the vicinity of the patient's head and face as clean as possible. Still further, we have observed that modification of the foot end of the selferecting airflow cover to define a non-inflatable but erectable drape section retains heat from the inflating medium to warm the patient's feet and insulate the bare skin of the feet from excessive heat from the inlet hose. Finally, we have observed that our self-erecting airflow cover may be advantageously adapted to thermally control

specific partial portions of the patient such as the legs and lower body or the arms and upper body, leaving other areas of the patient available for care and treatment. Moreover, an end portion of the cover may be adhesively attached to the patient to prevent the migration of air toward a care area. Finally, a protective sleeve may be slideably mounted on a connected heater tube adjacent the patient to prevent the heater tube from contacting the patient.

These observations have resulted in an improved thermal blanket and method therefor in which self-erecting inflatable covering has a head end, a foot end, two edges, and an undersurface. An inflating inlet adjacent the foot (or head) end admits a thermallycontrolled inflating medium into the covering. An aperture array on the undersurface of the covering exhausts the thermally controlled inflating medium from the covering into the structure created when the covering self-erects upon inflation. The improvements to this basic structural complement include an uninflatable section at the head (or foot) end of the covering, exhaust port openings at the edges of the covering, an absorbent bib or adhesive strip attached to the covering at the head (or foot) end adjacent the uninflatable section, an uninflatable erectable drape section at the foot end of the covering, a heater tube protective cover and structural features that make the covering simple and economical to produce. In the case of an upper body covering, the positions of the inflating inlet and the uninflatable section are reversed from that of other coverings. In the case of an upper body covering, the inflating inlet is positioned at the head end of the

covering while the uninflatable section is arranged at the foot end of the covering.

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With these improvements, the thermal blanket, when inflated and erected over a patient, delivers thermally-controlled inflating medium into the interior of structure covering the patient, thereby thermally The first improvement permits full bathing the patient. viewing of the head and face of the patient from almost any aspect around the thermal blanket. The exhaust port openings increase the rate of circulation of the inflating within the blanket, thereby increasing temperature within the structure and making the temperature distribution more uniform. The absorbent bib soaks up and retains liquids which might otherwise spread over the care site in the area of a patient's head or other body area. Such liquids can include the patient's own perspiration, blood, vomit, saliva, or liquids which are administered to the patient. The adhesive strip acts to seal the head (or foot) end of the inflated structure. The non-inflatable erectable drape section at the foot end of a covering encompassing the lower extremities retains heat around the patient's feet and insulates the bare skin of the legs and/or feet. The protective cover for the heater tube prevents an attached heater tube from contacting patient.

From another aspect, the invention is a thermal blanket for covering and bathing a person in a thermally-controlled medium. The thermal blanket includes a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures opening between the first and second surface of the base sheet. An overlying material sheet is

attached to the first surface of the base sheet by a plurality of discontinuous seams which form the material into а plurality of substantially -parallel, inflatable chambers. A continuous seam is provided between the material sheet and the base sheet at the head (or foot) end to form a non-inflatable viewing recess at the head (or Exhaust port openings are provided through the material sheet to vent the medium from the chambers away from the base sheet. An absorbent bib is attached to the head (or foot) end in the vicinity of the viewing recess. coverings encompassing the lower extremities. continuous seam is provided between the material sheet and the base sheet at the foot end to form a non-inflatable, erectable drape section to cover the patient's legs and/or feet.

Therefore the invention accomplishes the important objective of providing a self-erecting, inflatable thermal blanket that permits a relatively unobstructed view of a care site when in use.

Another objective is the efficient and uniform heating of the interior of the structure created when the blanket is inflated with a heat inflating medium.

A further objective is providing a covering for a patient's legs and/or feet that helps retain the heat inflating medium around the patient.

A still further objective is the provision of such a blanket with a means for maintaining the cleanliness of the care site.

A still further objective is to provide the ability to select coverings adapted for specific partial areas of the patient leaving other areas exposed for care and treatment. The advantageous simplified structure of the thermal blanket make its production straight forward and economical.

These and other important objectives and advantages will become evident when the detailed description of the invention is read with reference to the below-summarized drawings, in which:

Figure 1 is a side elevation view of a thermal blanket constructed in accordance with a first aspect of the invention, with the blanket in use, with associated thermal apparatus indicated schematically;

Figure 2 is an enlarged top plan view of the thermal blanket opened flat;

Figure 3 is an enlarged sectional view taken along 3-3 of Figure 2;

Figure 4 is a further enlarged sectional view taken along line 4-4 of Figure 3;

Figure 5 is a partial underside view of the thermal blanket;

Figure 6 is a partial diagrammatic top plan view of a thermal blanket constructed in accordance with a second aspect of the invention, with a partially constructed foot drape;

Figure 7 is a partial projected view of a fully constructed thermal blanket of Figure 6 in use, with the patient's feet illustrated by hidden lines underlying the foot drape;

Figure 8 is a top plan view of a partially constructed thermal blanket in accordance with a third aspect of the invention, for thermally covering the pelvic area and lower extremities of a patient;

Figure 9 is a partial projected view of a fully constructed thermal blanket of Figure 8 in use;

Figure 10 is a top plan view of a thermal blanket constructed in accordance with a fourth aspect of the present invention, for thermally covering the chest and upper extremities of a patient; and

Figure 11 is a partial projected view of a fully constructed thermal blanket of Figure 10 in use.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

When used herein, the term "thermal blanket" is intended to be interchangeable with, but not necessarily limited by, the term "airflow cover" used in our U.S. Patent No. 4,572,188, which is incorporated herein in its entirety by reference. In this description, the term "thermal blanket" is meant to invoke a self-erecting, inflatable structure for delivering a thermally-controlled inflating medium to the interior of the structure created when the thermal blanket is inflated. The purpose of the thermal blanket is to efficiently administer a uniformly thermally-controlled bath of the inflating medium to a patient within the erected structure.

Our invention is illustrated as we intend for it to be used in a first aspect without a foot drape in Figure 1. In Figure 1, a self-erecting, inflatable thermal blanket 10 has a head end 12, a foot end 14 and two lateral edges, one indicated by 15. An inflation inlet cuff 16 is connected to a heater/blower assembly 18 which provides a stream of heated air through a connecting hose 20. heater/blower 18 is operated, the stream of heated air flows through the inflating hose 20 into the thermal blanket 10 through the inflation cuff 16. When the blanket is inflated, it erects itself into a Quonset hut-like structure with a quilted upper surface 21. As described below, a pattern of apertures on the undersurface of the blanket (not shown in Figure 1) convectively delivers the inflating heated air into the interior space enclosed by the erected thermal blanket.

The contour of the inflatable portion of the thermal blanket 10 is varied at the head end 12 of the blanket to provide a non-inflated blanket recess 22 in the quilted upper surface 21, which remains smooth and flat when the blanket is inflated and erected. Circulation of the heating air is accelerated through the thermal blanket by exhaust port openings in the upper surface, adjacent the lateral edges of the blanket. Two exhaust ports openings are indicated by reference numeral 23. Further, a bib 24 made of an absorbent material is attached to the head end 12 of the thermal blanket in the vicinity of the non-inflated recess 22. In fact, as shown in Figure 1, the bib 24 includes a semi-circular tab 25 that extends into the recess 22.

As illustrated in Figure 1, the thermal blanket of the invention is inflated, erects itself into a bathing structure, and bathes a patient 26 with the thermallycontrolled air used to inflate the structure. patient is being thermally bathed, the uninflated recess 22 permits observation of the patient's head, face, neck, and chest from almost any location with respect to the thermal blanket 10. Thus, if the patient is placed on a gurney or a bed, the head of which is against a wall, a care giver such as a nurse, intern, resident, or doctor, can keep the patient's face under observation from the foot end 14 of the thermal blanket 20. Respiration can be detected by the rise and fall of the bib and uninflated area, which rest directly on the patient's chest. Moreover, the bib 24 will provide an absorbent sink for stray, unconfined liquids in the area of the patient's head or at the head end 12 of the thermal blanket 10.

Figure 2 is a plan view of the thermal blanket 10 opened flat to show details of its structure. illustrates the upper surface of the thermal blanket, that is the side that is visible in Figure 1. As seen, the upper surface consists of a parallel array of elongated tubes of which 30 and 32 are the lateralmost tubes, 34 is the center tube, and the tubes 38 are arrayed between one of the lateralmost tubes and the center tube. Each tube is separated from an adjacent tube by a discontinuous seam, one of which is indicated by 40. The seam 40 separates the tube 32 and its nearest adjacent neighbor 38. discontinuous seam 40 is interrupted by passageways 42 communicating between the tubes. An interrupted seam separates every tube from one adjacent neighboring tube. The seams permit the thermal blanket, when inflated, to assume a tubular structure on the upper surface, while the ports 42 permit full circulation of the inflating medium throughout the array of tubes. The foot-end seam 45 is continuous. The tubes are inflated through the center tube 34 which transitions to a port 36, through which the inflation cuff 16 is inserted. The edge seams 43 are discontinuous only at the exhaust port opening locations A seal can be made between the inflation port 36 and the inflation cuff 16 by any conventional means, example, an o-ring, or even tape. When the inflating medium is introduced into the center tube 34, it flows laterally from the center tube into all of the other tubes through the ports 42. Near the head end 12, a continuous seam 40 defines the forward end of all of the tubes, with the seam assuming a bell-curve shape. On the head end side of the seam 40, the thermal blanket 10 is uninflatable.

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The bell-shaped seam 40 thus defines the uninflatable area 22 at the head end of the thermal blanket 10, which is essentially coplanar with, or substantially parallel to, the underside of the blanket. As shown in Figure 1, by virtue of its structural integration with the rest of the thermal blanket 10, the non-inflated recess extends over the upper chest of the patient 26 when the blanket is However, since the recess 22 is uninflated, it inflated. provides a wide-angled viewing gap in the inflated contour of the upper surface 21. The gap is filled by continuation of the underside of the blanket. It is also noted that the pattern of inflatable tubes can be replaced by other suitable patterns of communicating, inflatable chambers. The tubes are preferred since they impart strength and shape to the erected bathing structure; other inflatable structures are contemplated, however.

The absorbent bib has an indent 44 cut into its outside edge, which permits the blanket to be drawn up to the chin of a patient and which provides absorbency laterally up the neck of the patient. The absorbent bib can consist of any absorbent material such as a single- or multi-ply tissue paper which is used to make paper towels.

Construction details of the thermal blanket 10 are illustrated in Figures 3 and 4. The thermal blanket 10 is assembled from a base sheet consisting of an underside layer 50 formed from flexible material capable of bonding to a layer 52 of heat-sealable plastic. For the layers 50 and 52, we have used a stratum of absorbent tissue paper prelaminated with a layer of heat-sealable plastic. Material of such construction is commercially available in production rolls and is used to make painters' drop

cloths. The upper side of the thermal blanket consists of a sheet of plastic bonded to the plastic layer 52 by an interruptible heat-sealing process to form the interrupted seams, one of which is indicated by 54, and the inflatable tubes, one indicated by 55. As can be seen in Figure 3, the interruption of the seam 54 forms a passageway 56 between adjacent tubes 55 and 57.

The absorbent bib and tab are shown in Figure 3 as a single material layer 60/58. Alternatively, they may be formed from separate material sheets cut to the outlines illustrated in Figure 2. The absorbent material forming the bib and tab can be bonded to the upper plastic layer by heat process or by gluing.

The inventors also contemplate deletion of the bib and tab. In this instance, the thermal blanket would still have the viewing recess, which would be defined by the continuous seam at the head end, and which would be filled with the forward portion of the base sheet.

Circulation of heated air through the blanket is enhanced by the exhaust port openings 23, which open through the upper plastic sheet sheet, which is heat sealed to the base of the blanket. The openings 23 vent the heated inflating air out of the outermost tubes 30 and 32, away from the underside of the blanket. Because air can circulate to, and through, the blanket edges, the inflating air in the outermost tubes is hotter than if the openings were absent. This results in hotter air being delivered through the underside apertures toward the edge of the blanket. We have measured the temperature distribution within the thermal blanket for inflating air which is heated to a medium temperature range and for inflating air

which is heated to a high temperature range. The results are provided in Table I for a blanket consisting of 13 tubes. Measurements of the temperature of air exhausted through underside apertures were made on the underside of each tube on one side of the blanket. The tubes are numbered 1-6, with 1 being the tube adjacent to the center tube, and tube 6 being the outermost tube adjacent on lateral edge of the blanket. Test apertures were made in the bottom of tube 6 only for the purposes of this test. As is evident, the distribution of temperature within the erected thermal blanket is more uniform when the exhaust port openings are provided. Further, provision of the exhaust ports also increases the average temperature within the erected structure of the blanket. Clearly, the provision of exhaust port openings at the lateral edges of the blanket delivers results which one would not expect when considering the operation of our thermal blanket with no exhaust port openings.

In our first preferred embodiment, the exhaust port openings are slits in the edge seams of our blanket. slits vary in length from 1-3/4 to 2 inches. Each edge seam is discontinuous approximately at each corner of the blanket so that inflating air is vented away form the underside of the erected blanket. This keeps relatively "colder" air at the blanket edges form mixing with the relatively "hotter" air exhausted into the structure through the underside apertures. The result is a "flatter" temperature profile of air within the blanket without the vents, which raises the temperature within the erected structure and makes the temperature distribution in the structure more uniform.

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Resultantly, the clinical effect of the blanket is enhanced. Heating is better controlled, and more uniform, with greater comfort to the patient.

TABLE I

	MEDIUM T RAN	EMPERATURE GE	Н		EMPERATURE ANGE
TUBE NO.	WITHOUT EXHAUST PORTS	WITH 2" EXHAUST PORTS	WITHOU F EXHAUS PORTS	T	WITH 2" EXHAUST ORTS
center (i	inlet) 113.3° F.	114.1° F.	121.3° F.	121.	3 <sup>0</sup> F.
Tube #1	109.9°	112.3°	117.3°	117.	7 <sup>0</sup>
Tube #2	105.3°	109.80	113.40	115.	00
Tube #3	103.20	107.1°	111.0°	113.	30
Tube #4	99.9 <sup>0</sup>	104.3°	101.40	108.6	5 <sup>0</sup>
Tube #5	97.2°	100.0°	95.7 <sup>0</sup>	104.	40
Tube #6 (outermos	st) 85.2 <sup>0</sup>	95.8°	89.6°	99.4	1 <sup>0</sup> .
Average tunder cov		106.7 <sup>0</sup>	108.4°	112.5	

The thermal blanket of the invention is enabled to bathe a patient in the thermally-controlled inflating medium introduced into the upper side tubes by means of a plurality of apertures 62 shown in Figures 4 and 5. The apertures extend through the underside of the blanket, which includes the layers 50 and 52. The apertures 62 are made in the footprints of the tubes of the blanket upper side according to a pattern which has been determined to deliver a very uniform thermal bath. In this regard, no apertures are provided through the underside into the lateral most tubes 30 and 32, or into the center tube 34. In addition, the apertures 62 are provided through the underside to the apertures in a density which varies

inversely with the proximity of the tube to the center tube Thus, the hole density increases from the tube 38a throughthe tube 38d. Even with the exhaust port openings, the temperature of the inflating medium exhibits a drop from the center to the lateral most tubes. density of the apertures 62 tends to reduce this gradient further by forcing hotter air to the edges of the blanket. Thus, the thermal bath delivered to the patient is of a generally uniform temperature. The aperture density variation also equalizes the flow of inflating medium out of the apertures. As will be evident, the inflating pressure will be greatest at the center tube 34 and will tend to diminish toward the lateral edges of the thermal Therefore, fewer apertures are required for the tubes near the center tube 34 to deliver the same amount of air as the relatively greater number of apertures in the tubes at a greater distance from the center tube 34.

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The apertures comprise openings which can be of any appropriate shape. For example, we have produced blankets with elongated apertures, approximately 1/4 inch in length.

Our invention is illustrated as we intend for it to be used in a second aspect including a foot drape in Figure 7. The foot end 14 of the thermal blanket 10 is modified to provide an uninflated drape forming section 70 formed by a rearward extension of the base sheet 50/52 and a noninflatable portion of the heat-sealable plastic bonded to the base sheet. The drape forming sheet 70 has sides 72 extending parallel to and rearwardly from the outside edge of the edge seams 43, and a rear edge 74. Optionally, the drape-forming sheet 70 further includes a pair of V-shaped cuts 76 in the rear corners thereof. The V-shaped cuts 76

are formed by converging cuts 78 and 80, extending inwardly from one of the sides 72 and the rear respectively, to a point of intersection 82. As-shown in Figure 7, the drape-forming section 70 may be formed into a foot drape 90 that includes a pair of side portions 92, a rear portion 94 and an upper portion 96. The drape 90 is so formed by joining the edges 78 and 80 of the V-shaped cuts 76 to form a pair of seams 98. To form the seams 98, the V-shaped cut edges 78 and 80 may be folded about respective lines 100 and 102 that parallel the edges 78 and 80, as shown in Figure 6. The resulting respective folded surfaces 104 and 106 may then be fastened together by appropriate means such as heat sealing. Joining the surfaces 104 and 106 forms a crease 108 and transforms the two dimensional drape forming section 70 into the three dimensional drape 90.

The resultant drape 90 is non-inflatable but erectable under the force of the heated medium circulating around the patient. The drape 90 thus traps and retains heat around the patient's feet to warm the feet. As shown in Figure 7, the drape 90 also insulates the bare skin of the feet from excessive conductive heat from the inflating hose 70 in the event the hose is oriented in a position wherein it might otherwise come in contact with the feet. Patient warming and comfort is thus further enhanced.

Our invention is illustrated as we intend for it to be used in a third aspect as an inflatable lower body covering in Figures 8 and 9. This covering warms convectively by exhausting warm air onto a patient. The thermal covering in this case is similar in all respects to the covering shown in Figs. 6 and 7, except that the covering may be shortened

to cover only the pelvic area and lower extremities of the Moreover, the head end of the covering may be modified to provide an open flat working area for the placement of instrumentation and to improve visualization of the care site, as shown in Fig. 9. As in the case of the thermal coverings discussed above, the covering 110 of Figures 8 and 9 includes a head end 112, a foot end 114, a pair of lateral edges 115, and an inflation inlet cuff 116 to which may be connected through a heater tube 20 to a heater/blower assembly such as the assembly 18 shown in Figure 1. As shown in Figure 9, the covering 110 may be inflated to form a Quonset hut-like structure with a quilted upper surface 121. Like the thermal covering 10, a pattern of apertures on the undersurface of the blanket 110 convectively delivers the inflating heated air into the interior space enclosed by the erected thermal blanket.

Alternatively, the head end of the quilted upper surface 121 could extend directly from one edge 115 to the other edge 115 without the provision of a non-inflated blanket recess 122, as shown in Fig. 8. Further, an adhesive strip 124 made of an adhesive material may be attached to the head end 112 of the covering 110 and extend between the edges 110. As shown in Fig. 8a, the adhesive strip 124 is mounted with its adhesive side oriented toward the base sheet, which includes an underside layer 150 formed from a flexible material capable of bonding to a layer 152 of heat sealable plastic. The layers 150/152 are formed in the same manner as the layers 50/52 shown in Fig. 3 and described above. Mounted to the underside of the adhesive strip 124 is a backing strip 125, which may be

positioned partially between the adhesive strip 124 and the layer 152 to prevent inadvertent peel-off.

As shown in Figure 9, the adhesive strip 124 may be adhered above the patient's pelvic and groin area to prevent the migration of air from inside the covering 110 to the care site. Moreover, the optional non-inflated recess 122 may be large and well-defined in order to improve visualization of the operating field and provide sufficient working area for resting instruments or other items during the rendering of care to a patient 126.

Like its counterpart covering 10, the covering 110 includes a parallel array of elongated tubes of which 130 and 132 are the lateralmost tubes, 134 is the center tube, and the tubes 138 are arrayed between one of lateralmost tubes and the center tube. The thermal covering 110 further includes a non-inflated yet erectable foot drape for retaining a thermal medium around patient's feet. As in the covering shown in Figure 6, the covering 110 is provided with a non-inflated drape forming section 170 extending rearwardly from the foot end 114. The covering 170 includes a pair of sides 172 and a rear edge 174. Moreover, the drape forming sheet 170 includes a pair of V-shaped cuts 176 in the rear corner thereof. shown in Figure 9, the drape forming section 170 may be formed into an erectable foot drape 190 that includes a pair of side portions 192, a rear portion 194, and an upper portion 196. As in the covering 10, the drape 190 of the covering 110 is formed by joining the edges of the V-shaped cuts 176 to form a pair of seams 198.

As with the longer full-body thermal blanket of Figs. 1 and 2, the covering 110 may be provided without a foot

drape as appropriate. In that case, it may be desirable to slideably mount a protective sleeve 200 over the heater tube 20 to prevent the tube from contacting the patient.

Advantageously, it will be observed that the lower body warming cover 110 maintains a thermal medium around the pelvic and groin area and lower extremities of the patient, while at the same time exposing the patient's torso and head as may be necessary for the provision of medical care and treatment to those areas.

Alternatively, or in combination with the lower body thermal covering 110, an upper body thermal covering 210 could be provided as shown in Figures 10 and 11. The upper body thermal covering 210 is structurally and functionally similar in most respects to the thermal coverings 10 and 110 discussed above. Thus, the thermal covering 210 includes a head end 212, a foot end 214; a pair of lateral edges 215, and an inflation inlet cuff 216 which may be connected through a heater tube 20 to an heater/blower assembly such as the assembly 18 shown in The thermal covering 210 further includes a quilted upper surface 22, which may have non-inflated recess 222 located at the foot end of the covering, as Thus, with the upper torso and arms of shown in Fig. 11. the patient being thermally bathed, the uninflated recess 222 permits observation of the patient's middle torso from almost any location with respect to the thermal covering 210.

Alternatively, as shown in Fig. 10, the quilted upper surface 221 could extend across the entire expanse of the covering between the edges 215 such that no uninflated recess 222 is formed. It is preferable in most cases,

however, to provide a recess 223 in the quilted upper surface 221 and the foot end 214 of the covering 210 to accommodate the curvature of the patient's torso, as shown in Fig. 11.

There may be additionally provided an adhesive strip 224 mounted to the foot end 214 of the covering 210. As shown in Fig. 10a, the adhesive strip 224 is mounted with the adhesive side facing the base sheet, which includes an underside layer 250 formed from a flexible material capable of bonding to a layer 252 of heat sealable plastic. The layers 250/252 are formed in the same manner as the layers 50/52 shown in Fig. 3 and described above. Mounted to the underside of the adhesive strip 224 is a backing strip 225, which may be positioned partially between the adhesive strip 224 and the layer 252 to prevent inadvertent peel-off. As shown in Fig. 11, the adhesive strip 224 may be adhered to the patient's torso to prevent the migration of air toward the care site.

covering 210 further includes an array elongated tubes of which 230 and 232 are the lateral most tubes, 234 is the center tube and the tubes 238 are arrayed between one of the lateral most tubes and center tube. addition, the thermal covering 210 includes a cutout area 240 centrally positioned at the head end 212 of the covering. The cutout 240 is formed by truncating the lateralmost tube 230 and an adjacent tube 238. The recess 240 permits observation of the patient's head and neck from almost any location with respect to the thermal blanket It also assists in thermally covering the patient's shoulders and arms without covering the patient's face. As shown in Figures 10 and 11, the bottom layer 250/252 of the

covering 210 may extend slightly beyond lateral edges 215 or the head end 212, or it may be coextensive therewith.

As shown in Figure 11, the thermal covering 210 is positioned over the patient's upper torso and arms so as to thermally control those areas while leaving the patient's lower torso exposed for the provision of care. indicated, the thermal covering 210 may be used alone or in combination with the thermal covering 110 depending on the location of the care site. Thus, various selected portions patient may be selectively warmed with illustrated thermal coverings while care and treatment may be rendered to other areas. In addition, a plastic head drape 260 may be adhesively mounted to the covering 210 over the patient's chest, and adjacent the head end 230. The plastic head drape 260 is placed over the patient's head and one or more vents 270 may be provided to direct warmed air to the head area.

In a preferred method of operation, one or both of the coverings 110 and 210 may be selectively employed on a patient to warm selected portions of the patient while permitting other portions to remain exposed for treatment. In utilizing the coverings 110 and 210, either alone or in combination, the covering 110 or 210 is first placed over the patient. The adhesive backing 125 or 225 is removed from the adhesive strip 124 or 224 and the adhesive strip is adhered to the patient to prevent the migration of air toward the care site. The hose 20 is then attached to the covering, an appropriate temperature is selected on the heater unit 18 and the unit 18 is activated. For the covering 110, the protective heater tube 200 cover may also be used when the cover does not include a foot drape. For

the covering 210, the head drape 260 may be adhered to the quilted portion 221 over the patient's chest and draped over the patient's head. As a final measure, a conventional blanket may be placed over the covering 110 or 210. During operation, the patient's temperature should be monitored regularly and the air temperature setting of the heater unit 18 adjusted accordingly.

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Many modifications and variations of our invention will be evident to those skilled in the art. For example, thermal coverings for additional selected patient areas could be implemented depending on the location of the care site and the need for thermally maintaining other areas. It is understood that such variations may deviate from specific teachings of this description without departing from the essence of the invention, which is expressed in the following claims.

We claim:

#### CLAIMS

1. In a self-erecting, inflatable thermal blanket for covering and bathing a person in a thermally-controlled inflating medium, the improvement comprising:

a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;

an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;

a continuous seam between said overlaying material sheet and said base sheet near said head end which closes ends of said inflatable chambers;

a non-inflatable section of said thermal blanket extending substantially between said continuous seam and said head end and including an end portion of said flexible sheet; and

said thermal blanket being sized to extend from a patient's pelvic and groin area to the patient's feet.

- 2. The improvement of claim 1 further including a non-inflatable foot drape.
- 3. The improvement of claim 1 further including an adhesive strip at said head end to adhere said head end to a patient and prevent migration of air towards a care site.

- 4. In a self-erecting, inflatable thermal blanket for covering and bathing a person in a thermally-controlled inflating medium, the improvement comprising:
  - a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;
  - an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;
  - a continuous seam between said overlaying material sheet and said base sheet near said head end which closes ends of said inflatable chambers;
  - a non-inflatable section of said thermal blanket extending substantially between said continuous seam and said head end and including an end portion of said flexible sheet; and

said thermal blanket being sized to extend from a patient's neck to the patient's upper torso and to cover the patient's arms and shoulders.

5. The improvement of claim 4 further including a flat uninflatable section at said foot end.

)

6. The improvement of claim 4 further including an adhesive strip at said foot end to adhere said foot end to a patient and prevent migration of air towards a care site.

- 7. The improvement of claim 4 further including a head drape at said head end to drape over a patient's head and a vent for directing heated air under said head drape.
- An inflatable thermal blanket for convectively
   controlling the temperature of a human body, comprising:

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a self-erecting inflatable covering with a head end, a foot end, two edges, and an undersurface;

an inflating inlet for admitting a
thermally-controlled inflating medium into said
covering;

an array of apertures in said undersurface for exhausting a thermally controlled inflating medium from said covering to said undersurface;

means in said inflatable covering for equalizing the temperature of a thermally controlled inflating medium in said inflatable covering by circulating said inflating medium toward said two edges;

an uninflatable extension in said inflatable covering at said head end; and

said thermal blanket being sized to extend from a patient's pelvic and groin area to the patient's feet.

- 9. The thermal blanket of claim 8 further including a non-inflatable foot drape.
- 10. The thermal blanket of claim 8 further including an adhesive strip at said head end to adhere said head end to a patient and prevent migration of air towards a care site.

11. An inflatable thermal blanket for convectively controlling the temperature of a human body, comprising:

a self-erecting inflatable covering with a head end, a foot end, two edges, and an undersurface;

an inflating inlet for admitting a thermally-controlled inflating medium into said covering;

an array of apertures in said undersurface for exhausting a thermally controlled inflating medium from said covering to said undersurface;

means in said inflatable covering for equalizing the temperature of a thermally controlled inflating medium in said inflatable covering by circulating said inflating medium toward said two edges;

an uninflatable extension in said inflatable covering at said head end; and

said blanket being sized to extend from a patient's neck to the patient's upper torso and to cover the patient's arms and shoulders.

- 12. The thermal blanket of claim 11 further including a flat uninflatable section of said foot end.
- 13. The improvement of claim 11 further including an adhesive strip at said foot end to adhere said foot end to a patient and prevent migration of air towards a care site.
- 14. The improvement of claim 11 further including a head drape at said head end to drape over a patient's head and a vent for directing heated air under said head drape.

- 15. In a self-erecting, inflatable thermal blanket for covering and bathing a person in a thermally-controlled inflating medium, the improvement comprising:
  - a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;
  - an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;
  - a continuous seam between said overlaying material sheet and said base sheet near said head end which closes ends of said inflatable chambers;
  - a non-inflatable section of said thermal blanket extending substantially between said continuous seam and said head end and including an end portion of said flexible sheet; and
  - a flexible heater hose attached to said thermal blanket to provide heated air to said inflatable chambers, said flexible heater hose including a protective sleeve slideably disposed thereon to prevent hose contact with a patient.
- 16. An inflatable thermal blanket for convectively controlling the temperature of a human body, comprising:
  - a self-erecting inflatable covering with a head end, a foot end, two edges, and an undersurface;
  - an inflating inlet for admitting a thermally-controlled inflating medium into said covering;

an array of apertures in said undersurface for exhausting a thermally controlled inflating medium from said covering to said undersurface;

means in said inflatable covering for equalizing the temperature of a thermally controlled inflating medium in said inflatable covering by circulating said inflating medium toward said two edges;

an uninflatable extension in said inflatable covering at said head end; and

a flexible heater hose attached to said thermal blanket to provide heated air to said inflatable chambers, said flexible heater hose including a protective sleeve slideably disposed thereon to prevent hose contact with a patient.

17. A method for thermally warming a selected portion or portions of a patient for rendering care to other portions of the patient, comprising the steps of:

selecting one or more inflatable thermal blankets sized to cover a portion or portions of a patient to be thermally warmed so that care may be administered to other portions of the patient, said inflatable thermal blanket(s) being of a type that comprise(s):

a self-erecting inflatable covering with a head end, a foot end, two edges, and an undersurface; and

an inflating inlet for admitting a thermally-controlled inflating medium into said covering;

an array of apertures in said undersurface for exhausting a thermally controlled inflating medium from said covering to said undersurface;

means in said inflatable covering for equalizing the temperature of a thermally controlled inflating medium in said inflatable covering by circulating said inflating medium toward said two edges;

an uninflatable extension in said inflatable covering at said head end or said foot end; and

an adhesive strip at said head end or said foot end having an adhesive portion facing in the direction of said thermal blanket undersurface and a removable backing covering said adhesive portion;

said method further comprising the steps of:

placing the thermal blanket(s) over the portion(s) of the patient to be thermally warmed such that the adhesive portion of said blanket(s) is oriented toward a care site;

removing the backing from said adhesive portion and adhering the adhesive to the patient to prevent the migration of air towards a care site;

attaching a heating tube or tubes from a heating unit to said thermal blanket(s);

selecting an appropriate temperature and activating the heating unit; and

monitoring the patient's temperature regularly and adjusting the heating unit temperature as required by the patient's temperature.

- 18. The method of claim 17 wherein the area(s) of a patient to be covered include(s) the area extending from the patient's pelvic and groin area to the patient's feet.
- 19. The method of claim 18 wherein said thermal blanket extends from the patient's pelvic and groin area to the patient's feet and wherein the adhesive portion of said thermal blanket is adhered to the patient above the patient's pelvic and groin area.

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- 20. The method of claim 19 further including the step of placing a protective sleeve over the heater tube adjacent said thermal blanket to prevent the heater tube from contacting the patient.
  - 21. The method of claim 17 wherein the area(s) of a patient to be covered include(s) the area extending from the patient's neck area to the patient's chest and including the patient's arms.
  - 22. The method of claim 21 wherein said thermal blanket extends from the patient's neck area to the patient's chest and also covers the patient's arms and wherein the adhesive portion of said thermal blanket is adhered to the patient's chest.
  - 23. The method of claim 22 further including the step of adhering a head drape on or near said head end of said thermal blanket and draping the head drape loosely over the patient's head.

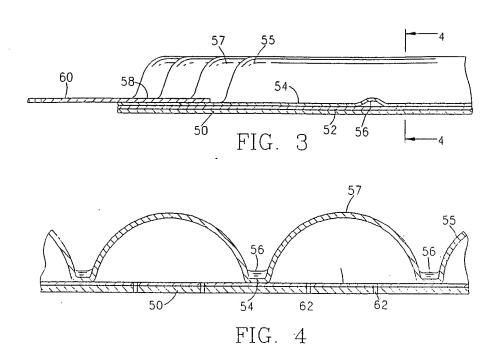
- 24. The method of claim 17 further including the step of draping a conventional blanket or blankets over said thermal blanket(s).
- 25. A thermal care system for thermally warming a patient comprising:
  - an inflatable thermal blanket having at least one inflatable chamber therein and an air inlet for admitting air to said chamber;
  - a heater/blower assembly providing a source of heated air;
  - a heater tube extending from said heater/blower assembly to said thermal blanket air inlet; and
  - a protective sleeve slideably disposed over said heater tube adjacent said thermal blanket air inlet to prevent said heater tube from contacting the patient.

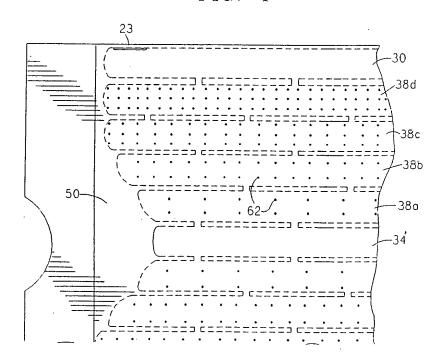
#### THERMAL BLANKET

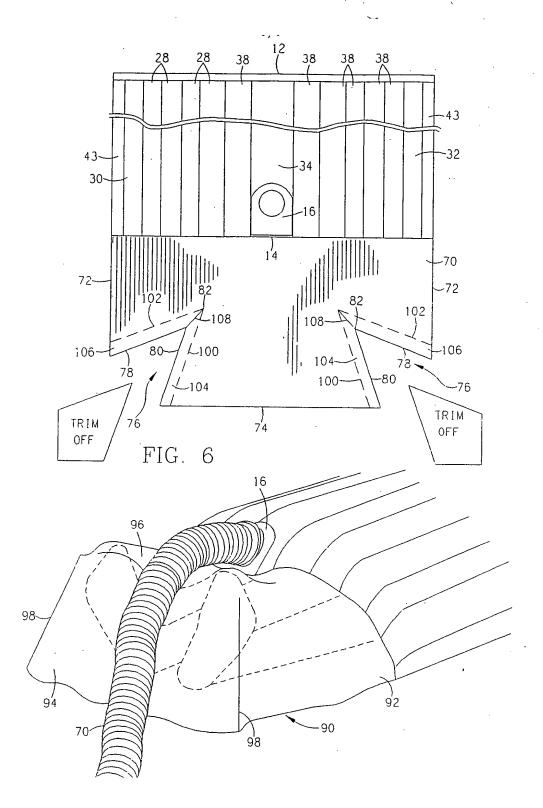
#### ABSTRACT

A thermal blanket includes an inflatable covering with a head end, a foot end, two edges and an undersurface. covering is inflated through an inlet at the foot end by a thermally-controlled inflating medium. An aperture array on the undersurface of the covering exhausts the thermally controlled inflating medium from the covering. port openings are provided that the edges of the covering to vent the inflating medium, which enhances circulation of the thermally-controlled medium through the cover. uninflatable section is provided at the head end, together with an absorbent bib attached to the covering, adjacent the uninflatable section. An uninflatable section may also be provided at the foot end having a pair of seams to form an erectable drape section. When inflated, the thermal blanket self-erects and provides bath thermally-controlled inflating medium to the interior of the erected structure. The enhanced circulation of the medium through the covers maintains a relatively high average temperature under the blanket and a relatively uniform distribution of temperature in the inflating medium which is exhausted through the apertures structure's interior. When the structure covers a patient, the uninflatable section at the head end provides a relatively unobstructed view of the patient's face, while absorbent bib maintains a relatively sanitary environment in the area beneath the patient's head. uninflatable section at the foot end retains heat from the

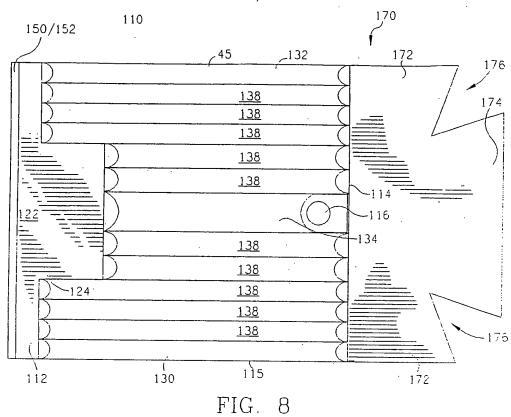
inflating medium to warm the patient's feet and insulate the bare skin of the feet from excessive conductive heat from the hose connected to the inflation inlet. The thermal blanket may be sized to cover selected areas of a patient such as the upper body, including the chest, arms, or shoulders, or the lower body, including the pelvic and groin area and the legs.







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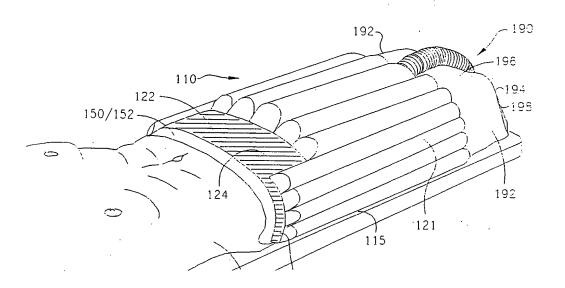
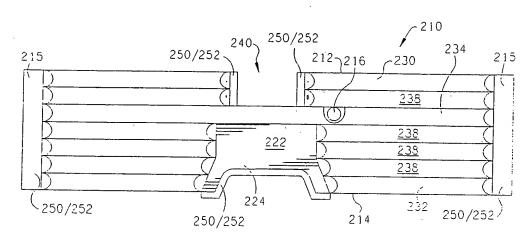
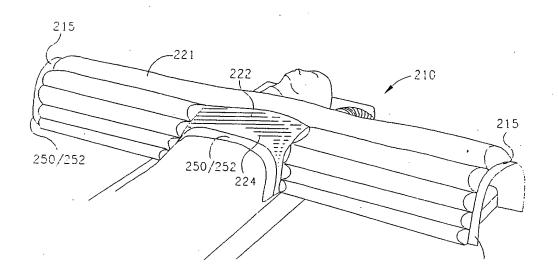


FIG. 10





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As a below named inventor, I hereby declare tha .:

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# Page 2/Declaration/Power of Attorney

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S. GOLDSCHMIDT. Surgical-Bandage.

Patented Dec. 16, 1879. No. 222,690. Fig.1. Fig.3. Fig. 7. Fig.5. Fig.Y.

WITNESSES:

Care Horn.

Otto Ruch

INVENTOR:

Samuel Geldschmidt

BY

ATTORNEY.

## STATES PATENT

SAMUEL GOLDSCHMIDT, OF BERLIN, PRUSSIA, GERMAN EMPIRE.

## IMPROVEMENT IN SURGICAL BANDAGES.

Specification forming part of Letters Patent No. 222,690, dated December 16, 1879; application filed July 21, 1879.

To all whom it may concern:

He it known that I, SAMUEL GOLDSCHMIDT, of Berlin, Prussia, German Empire, have invented an Improved Surgical Bandage, (cataplasm,) of which the following is a specifica-

In the accompanying drawings, Figures 1 and 2 represent perspective views of my improved surgical bandage, shown as applied, respectively, to a part of and to the entire body. Figs. 3, 4, 5, 6, 6, 7, 8, and 9 are detail views of the bandage, shown as adapted to be applied, respectively, to the leg, arm, abdomen, head, vagina, rectum, or other part of the body.

Similar letters of reference indicate corre-

sponding parts.

This invention relates to improved ventilating bandages for cooling or heating any part of or the entire body in a clean, uniform, and reliable manner; and the invention consists of bandages of water-proof material having ven-

tilating openings or passages.

In the drawings, A represents my improved bandage, which is made in the shape of a cushion of elastic and water-proof material, and of any desired shape, large or small, so as to be adapted for any part of or for the entire body. The bandage is of greater or less thickness, and provided either with tubes or openings B, according to the thickness of the bandage. These tubes or openings pass transversely through the bandage, and admit the passage of the air to the inside of the same. One end of the bandage is connected by a tube, a, b, or c, with an elevated supply-reservoir containing warm or cold water, the temperature of which is regulated by means of ice for cold applications, or by a spirit-lamp and thermometer for warm cataplasm. At the lower end or part the water is conducted off by a discharge tube, a', b', or c', which leads to a suitable vessel. Both the inlet and outlet tubes are provided with stop-cocks for properly regulating the circulation of water.

The transverse ventilating tubes or open-

ings I have not only the advantage of admitting atmospheric air, but also of admitting the escape of vapor, &c. They further effect a better distribution of the water, so that a more uniform temperature throughout the en-tire bandage is obtained. The openings also admit the application of cooling, disinfecting, or other medicaments, such as carbolic acid, &c., without being obliged to take off the bandage.

My improved ventilating bandages have the following advantages: First, the handage can remain permanently in position, and need not be changed, so as to annoy the patient; second, the temperature of the bandage can be accurately regulated; third, the bandage incloses entire parts, and fits snugly and comfortably thereto; fourth, full ventilation by access of air and escape of vapors is obtained; fifth, the bandage exerts no pressure, owing to its reduced size; sixth, it forms in many cases an effective and convenient substitute for the permanent baths applied to the entire body or parts thereof.

I am aware that bandages formed of double walls, between which a cooling or heating medium passes, are well known, and I do not claim

the same, broadly.

Having thus described my invention, I claim as new and desire to secure by Letters

Patent-A surgical bandage formed of double walls-

of water proof material, said walls being con-nected by a number of transverse passages, which provide openings for the access of air to the skin, and around which the liquid circulates, substantially as and for the purpose set forth.

In testimony whereof I have signed my name to this specification in the presence of two subscribing witnesses.

SAMUEL GOLDSCHMIDT.

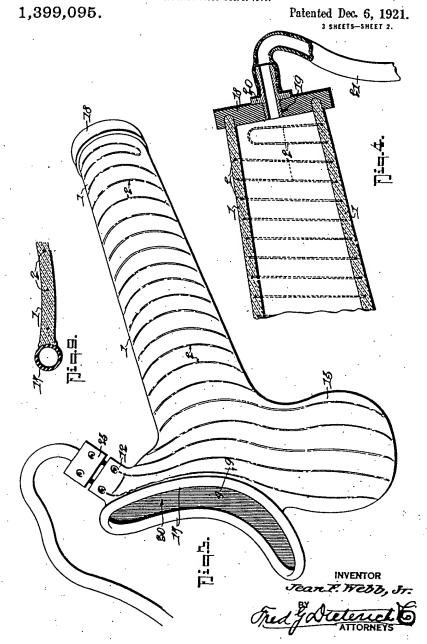
Witnesses:

H. KREISMANN, EDWARD P. MACLEAN.

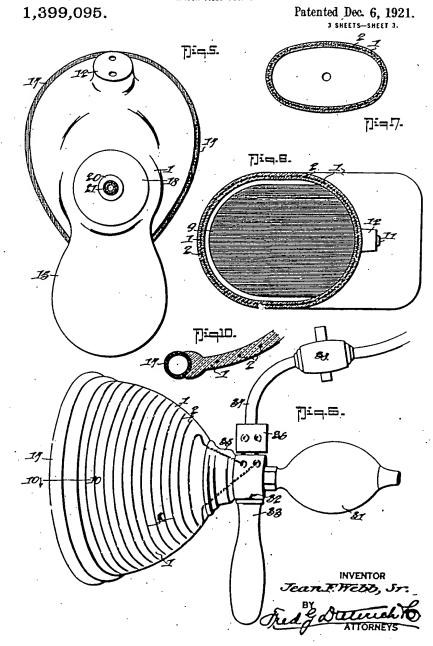
J. F. WEBB, Sr.
VACUO THERMIC BODY TREATMENT APPLIANCE.
APPLICATION FILED DEC. 2, 1919.

1,399,095. Patented Dec. 6, 1921. 72.2. ٦<u>٠=</u>-1. INVENTOR
Tean F. Webb,

J. F. WEBB, Sr.
VACUO THERMIC BODY TREATMENT APPLIANCE.
APPLICATION FILED DEC. 2. 1919.



J. F. WEBB, Sr.
VACUO THERMIC BODY TREATMENT APPLIANCE.
APPLICATION FILED DEC. 2. 1919.



istic of my invention is maintained and they comprise essentially a bulbular body having the electric heating coils 2 embedded therein, for generating the heat, a switch connection,

s preferably attached to the body, and a connection on the body for the attachment thereof of an air or vacuum creating bulb, and when the member or part being treated is to be entirely incased, suitable means is 10 attached to the body for making an air tight' closure at the open end of the body.

As shown in Fig. 1, the body 1 is of a bulbular shape and of a size suitable for receiving therein the hand and the wrist of the 15 user, it being understood that the said body 1, may be long enough to extend to near the elbow, to adapt it for the ready treatment of

a sprained wrist or forearm.

At the open end, the body 1, shown in 20 Fig. 1, is restricted and it there terminates in a tubular extension 10 which provides for the convenient attachment thereto of a broad sheet rubber band 3 that aids in keeping the attachment in the desired operative position and also effects an air tight closure for the hollow body.

In the form referred to, the body 1 at the outermost end has a tubular nipple or extenin 11, for receiving the end of a flexible 30 hose 4 of an ordinary vacuum bulb device 40, which, when manipulated in the usual way, draws the air from and creates a vacuum

within the said body 1.

At a suitable point, preferably at the straight neck, the body 1 is formed with a coupling block 12, designed for receiving the ordinary type of plug switch 6 and which may have the usual regulating lever 60 for controlling the strength of the current that 40 passes through the heat coils 2.

It should be stated that in practice, the wire cord 7 is supplied with the usual form of switch plug for connecting with the house electric light fixtures or to a battery.

In Fig. 2 is shown substantially the same form of appliance illustrated by Fig. 1, except that the hollow body is shaped for receiving the leg or foot, and the nipple 11 for attaching the vacuum creating bulb device is located below and adjacent the coupling

In this latter form, a rubber closure band 8 is also used and it engages the neck portion 13 of the body and the leg to make the air 55 tight closure for the upper end.

While the form shown in Fig. 2 is esp cially adapted for receiving the foot and the leg below the knee, it is obvious the body 1 may be of sufficient length to include the 60 knee joint, and in this latter form, an asbes-tos plate 9 is located on the bottom of the body 1 to avoid burning the foot.

The form shown in Fig. 2 is especially well adapted for the treatment of gout, From the foregoing description taken in so varicose veins in the leg and sprained ankles connection with the drawings, the complete 130

and, when made long enough, for the treatment of rheumatic and other diseases of the knee.

Vacuum tubes for the male organ alone have long been known or used, but they did 70 not inclose the orches (testicles), the seat of the varicocele; and consequently they could not furnish the proper treatment needed to relieve congested or abnormal conditions in all the parts.

Fig. 5 illustrates a further form of my improved appliance that is particularly designed for use for effecting the proper treatment of those parts last referred to and, in the said form, the body 1 includes, in addi- 80 tion to the bulbular body portion 1, a sack-like member 15 for receiving the orches, and a vacuum cup-like open end 30, the cup-like open end being shaped to conform to the contour of the pelvis and the thighs, and to 85 provide an air tight closure, as the appliance is pressed tightly against the body, the said cup-like edge has a flange on which is received a rubber gasket 17 cemented or otherwise made fast to the said edge.

In this latter form of my appliance, the outer end of the glass body 1 which is in the nature of a tube, is closed by a disk 18 (preferably hard rubber) provided with an internally threaded aperture 19, for receiv- 95 ing the threaded coupling 20 on the end of the flexible tube 21 that joins with the air exhausting rubber bulb 40 provided with the usual valve devices 23—24 in the oppo-

site ends thereof, as shown.

Near the inner end, the body 1 has the switch portion for connection with the switch plug 25 on the end of the electric conduit cord that joins with the source of elec-

tric supply.

In Fig. 6 is shown a still further modification of my invention, the said form being especially designed for cupping on the local applications to any part of the human body, and in the said form, the body 1 is also provided with a rubber covered edge or rim to provide for an air tight closure as the appliance is held pressed against the part of the human body to be treated.

In the latter construction, the body 1 is 115 bowl-shaped and has its crown or inner end secured air tight in any suitable manner, to a head portion 35 that constitutes a block for receiving the circuit closing member 36 to which the current wire lead 37 connects, 120

38 designates a central switch in the cord or lead 37 for coupling with the source of

electrical energy.

Block 35 has an aperture that opens into the bowl-shaped body and with which connects the stem of a vacuum bulb 31 and it also has a socket 32 for receiving a hard rubber handle 33.

construction of, the manner in which the appliances may be used and the advantages thereof will be especially apparent to those familiar with the use of appliances of the 5 character stated.

Among many other advantages of my invention, it should be mentioned that the same may be readily shaped in various forms suitable for the treatment of different parts, or members, of the human body and capable of being readily adapted for use by connecting the appliance with a house service elec-

tric plug or battery.

The patient can easily apply the appliance
and maintain it at the desired positions for
the special treatment desired, and by reason
of having the switch connections and the
vacuum devices combined with the appliance
as shown and described, the user can apply
the heat treatment or the vacuum treatment
either alternately or together and by observation, he can regulate either curative agent
as conditions may make desirable for effect-

ing a speedy and effective cure.

While I have illustrated a number of forms of my invention, to illustrate the adaptability of the same for the treatment of various parts of the body, it is understood appliances either larger or smaller sizes for the treatment of the full length of leg, individual fingers, elbows or other joints may be

readily made without in the least departing

from the generic form of my invention as comes within the scope of the appended claims.

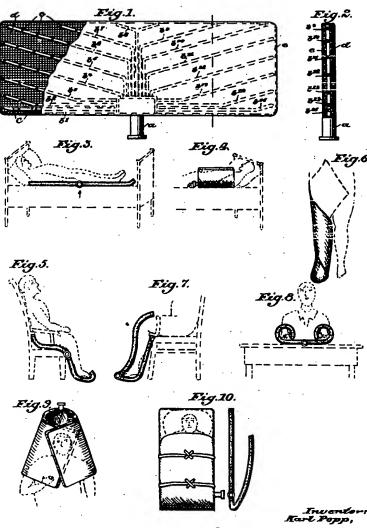
What I claim is:

1. A vacuo-thermic appliance comprising a container of transparent heat resisting material, electric circulation wires embodied in the entire outside transparent shell of the said container, a circuit closure connected with the said container, the latter being provided with an open end adapted for being secured air tight against the human body, a source of electrical energy connected with the circuit closure and means attached to the container for effecting vacuum within the container, as desired.

2. As a new article, a vacuo-thermic medical appliance that comprises a container open at one end into which may be received a part of the human body to be treated, heat coils embedded in the shell of the container, a block that constitutes a closure for the other end of the container and into which the terend of the container and into which the terminals of the heat coils extend, a circuit closure in connection with the said terminals, the said block having an air passage in communication with the interior of the container and a vacuum creating bulb attached to the said block and in communication with the air passage therethrough.

JEAN F. WEBB, SR.





Langue Parry land Hangua

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## UNITED STATES PATENT

#### EARL POPP, OF PLANITS, GERMANY

#### HOT-ATE MAT

Application fled Funs 10, 1939, Serial Wo. 300,743, and in Germany February 30, 1988.

This invention relates to a hot air mat for controllable air distribution is obtained and, use in the treatment of disease and also for other purpos

The present invention seeks to remove the s disadvantages of the prior art and is based, whilst avoiding any rigid frame, on the ides of placing the tube system, which was hitherto rigid and fixed to the mat, in the mat itself, in such a manner that, instead of the to above, flexible metallic tubes are used and are permanently fixed inside the mat, so that the mat. their position cannot vary.

The system of tubes is fan-shaped which, 100 system of tubes is lan-suspect which,
15 in no way, hinders the rolling up or adaptability of the mat, but imparts, in the manner of the bones of a fish, and in spite of maintaining the flexibility, such a degree of permanence in shape and protection against 20 compression, that resistance is offered to any

possible outside influence.

Thus the whole of the drawbacks enumerated above are eliminated. The patient can be wrapped in the new mat as quickly as and as easily as in an ordinary quilt, and also a thorough and uniform distribution of hot sir is engured as the distribution. of hot air is ensured, as the distance between the top and underside of the mat is main-tained constant by the flexible metal pipes so themselves, thereby ensuring the passage of air under all circumstances.

The metallic tubes, according to the present invention are embedded in a wire netting, whereby any heat which may natu-stally become stored up in the walls of the tubes is uniformly distributed and simulta-neously, the certain degree of stiffness of the wire netting which exists in spite of the flexibility prevents. flexibility, prevents any sagging of the cov-ering layer of the mattress or mat which might endanger the distribution of the air. The relatively stiff wire netting takes up uniformly the pressure of the patient's body so that the patient is not troubled by localized pressure of the fish-bone-like embedded tubing.

The present invention, however, makes use of ordinary flexible metallic tubing, in the practically rigid walls of which separate so holes are provided. In this way a strictly

if necessary, by varying the distance between the holes the distribution can always be

effected perfectly.

In the drawing is shown diagrammatically as an embodiment of the invention.

Fig. 1 is a plan view of the improved mat, with the upper layers partly removed.

Fig. 2 is a side elevation of Fig. 1 partly

Figs. 8-10 show various methods of using

The air, heated in any desired manner, enters a pipe a, and is thence distributed, for example into fifteen metallic tubes b'-b'

(first distribution), and then passes through pecially distributed holes o in the tubes second distribution) into a hollow space formed by wire netting d and a removable, washable fabric covering e, and in which to space an additional exchange of pressures, air and heat takes place, whereupon the hot air passes out through the fabric covering in ex-tremely fine and uniform distribution (third distribution). Both the exit and closing of 75 the air can be effected according to requirements, on either side and in fact at any desired point. The mat fits any standard bed and any couch or standard sized sofs, whilst by means of the same warming, airing and 60 drying and various packings and wrappings air or steam baths can be effected. Figs. 3-10 show a number of examples of use.

Fig. 3 shows the mat used as an air, hot-air or steam bath. In this arrangement the hot as air mat may be used for warming, airing and drying of beds.

Fig. 4 shows a partial hot air bath for back, breast and body.

Fig. 5 shows the same arrangement for the 90 buttocks and the two legs (also recumbent position'

Fig. 6 shows a like arrangement for one

leg. 7 shows an arrangement for the knee, 26 lower leg and feet of both legs (also recumbent position).

The Cohomothe same arrangement for both

arms. Also adaptable by rolling singly for one arm only.

The arrangements according to Figs. 8-8 may also be used with suitable packings, wrappings and the like as a heat distributing

wrappings and the like as a heat distributing layer.

Fig. 9 shows an arrangement for treating the head, neck, the wind pipes—hot air inhalation—and the shoulder, and Fig. 10 shows the use of the mast as hot air bed for children or prematurely born children (in this case air-douch with temperature recordators)

oren (in this case air-douch with temperature regulator).

in addition the mat can serve directly for warming the seats of motor cars, electric railways and the like and indirectly for heating the latter.

What I claim is:

What I claim is:

1. A hot air mat comprising a covering, a wire netting therein, flexible metallic tubing embedded in said wire netting, a common hotair inlet for the tubing, and means in the wall of the tubing permitting the passage of air.

2. A hot air mat comprising a porous fabric covering, a wire netting therein, flexible metallic tubing embedded in said wire netting, a common hotair inlet for the tubing, and means in the wall of the tubing permitting the passage of air.

3. A hot air mat comprising a covering, a wire netting therein, flexible metallic tubing spread out and fixed in said netting, outlet holes in said tubing, and at least one means for supplying air to the tubing.

4. A hot air mat comprising a porous fabric covering, a wire netting therein, flexible metallic tubing spread out and fixed in said wire netting, outlet holes in said tubing, a common air chamber connected with the tubing, and means for feeding the air chamber with heated air.

40 In testimony whereof I have signed my name to this specification.

KARL POPP.

KARL POPP.

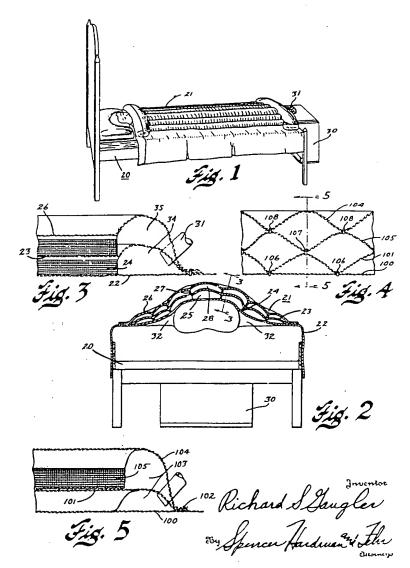
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R. S. GAUGLER
REFRIGERATING APPARATUS

Filed April 30, 1934

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Sheets-Sheet 1



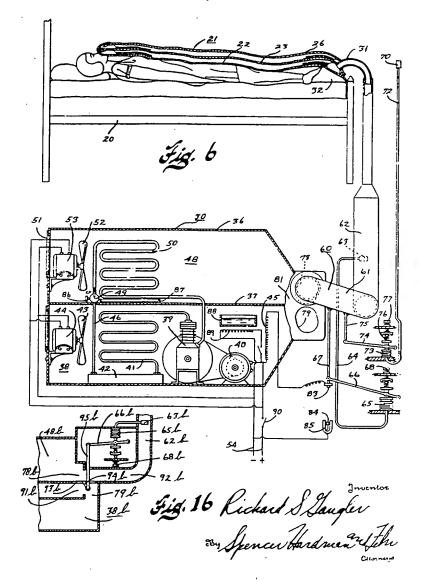
R. S. GAUGLER

REFRIGERATING APPARATUS

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Filed April 30, 1934



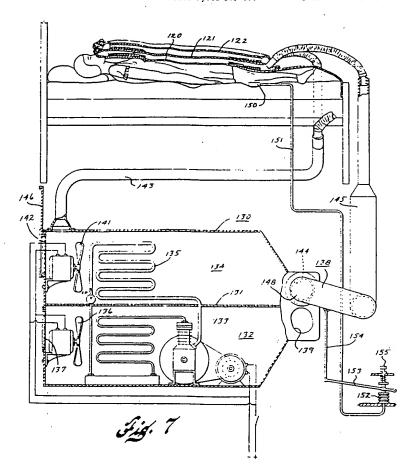
R S. GAUGLER

REFRIGERATING APPARATUS

Filed April 30, 1934

6 Sheets-Sheet 3

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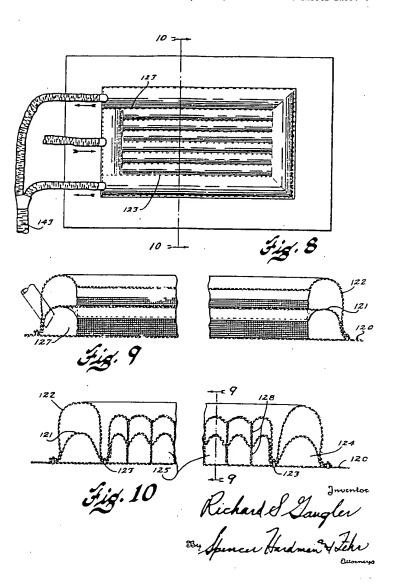
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R. S. GAUGLER
REFRIGERATING APPARATUS

Filed April 30, 1934

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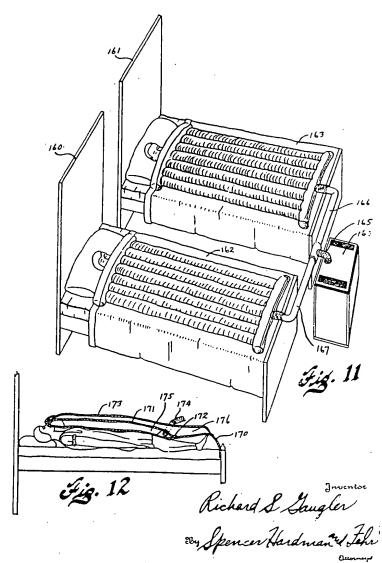
R. S. GAUGLER

REFRIGERATING APPARATUS

Filed April 30, 1934

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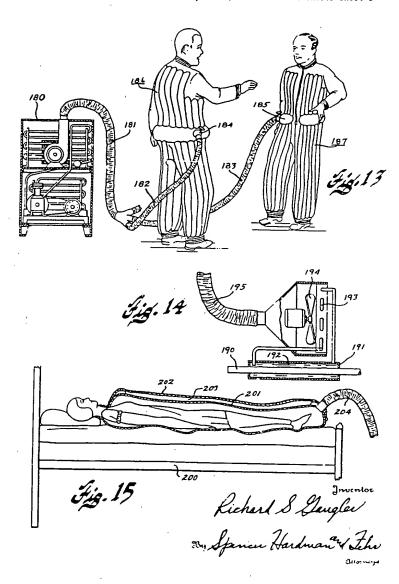
R. S. GAUGLER

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REFRIGERATING APPARATUS

Filed April 30, 1934

6 Sheets-Sheet 6



### UNITED STATES PATENT OFFICE

#### 2.093.834

#### REFRIGERATING APPARATUS

Richard S. Gaugier, Dayton, Ohio, assignor to General Motors Corporation, Dayton, Ohio, a corporation of Delaware

Application April 30, 1934, Serial No. 723,078

11 Claims. (CL 128-145)

This invention relates to refrigerating apparatus and more particularly to a personal type of air conditioning.

Heretofore air conditioning equipment has been 5 required to condition the air within the entire room or space occupied by persons desiring the comfort of air conditioning. If air conditioning were confined to the immediate vicinity of such persons, the equipment would be much less expense. An application of this scheme which appears to have great possibilities is that of air conditioning beds since every one spends a continuous period of about one-third of each day in 15 hed.

Attempts have been made to provide air conditioning enclosures for beds, some of which provide a complete enclosure for the bed while another merely provides curtains around the sides of the bed into which the cool air is introduced and confined therein by gravity. The general public, however, is unaccustomed to such enclosures and would experience a feeling of confinement which would prevent their widespread use. In addition, the initial cost of such enclosures is considerable and the operating expenses, while less than for a complete room, are still sufficiently high to prevent their use for those of limited means.

I. by my invention, propose to overcome these objections and to provide a personal type of air conditioning means which in outward appearance and in its use is little different from those replaced thereby and which also is sufficiently low in initial cost and operating expense to permit its purchase and use by persons of limited means. My air conditioned enclosure employs a cover-

My air conditioned enclosure employs a covering or enclosure for the body very similar as to material as well as to use and appearance to that now in ordinary use providing therein a means for diffusing the discharge of conditioned air over and surrounding the body to provide an air conditioned environment for the body as well as providing insulating air pockets, and to this enclosure I supply conditioned air or treating medium from a small inexpensive air conditioning or treating device capable of heating and cooling the air as required at a low operating cost.

More specifically I provide a covering for the body formed of ordinary fabric cloth or sheeting in a plurality of layers sewed or held together to form a plurality of enclosures into one of which I supply the conditioned air or treating medium from which some of the air diffuses through the sheeting into contact with the body to provide an

air conditioned environment for the body while some air diffuses through the sheeting into a second enclosure to form an inflated insulating air layer.

Purther objects and advantages of the present 5 invention will be apparent from the following description, reference being had to the accompanying drawings, wherein a preferred form of the present invention is clearly shown.

In the drawings:
Fig. 1 is a perspective view of one form of my

invention;
Fig. 2 is a transverse sectional view through the mid portion of Fig. 1;

Fig. 3 is a fragmentary sectional view taken 15 along the line 3-3 of Fig. 2;

Fig. 4 is a modified fragmentary section similar to that shown in Fig. 2;

Fig. 5 is a sectional view along the line 5—5 of Fig. 4:

Fig. 6 discloses a longitudinal sectional view of the bed shown in Fig. 1 together with a diagrammatic illustration of the air conditioning apparatus and system therefor; Fig. 7 discloses a sectional view of a bed to-

Fig. 7 discloses a sectional view of a bed together with an air conditioning system, shown diagrammatically, illustrating a modified form of my invention embodying recirculation of the air:

Fig. 8 is a plan view of the air blanket shown in 30 Fig. 7:

Fig. 9 is a longitudinal sectional view of the air blanket shown in Fig. 8 taken along the line

9-3 of Fig. 10;
Fig. 10 is a transverse sectional view of the air 55 blanket taken along the line 10—10 of Fig. 8;

Fig. 11 is a perspective view disclosing a multiple air conditioning system embodying my invention applicable to twin beds:

Fig. 12 is a longitudinal sectional view through 40

Fig. 12 is a longitudinal sectional view through a bed embodying another form of my invention; Fig. 13 discloses another application of my invention, particularly intended for persons required to work in hot or cold places.

vention, particularly intended for persons required to work in hot or cold places;
Fig. 14 discloses a heating apparatus for the 45 air conditioning suits shown in Fig. 13 suitable for use in an eighbor and

for use in an airplane, and
Pig. 15 discloses another application of my invention in the form of z sleeping bag.

vention in the form of z sleeping bag.

Fig. 16 is a diagrammatic view of a simplified 50 form of control apparatus.

Referring to the drawings and more particularly to Fig. 1, there is shown an ordinary wooden bed 20 provided with springs, a mattress and a pillow in the usual manner together with the 55

usual sheet covering the mattress. However, Instead of the ordinary blankets or other bed clothing, I provide what I term an air blanket generally designated by reference character 21. This
are blanket preferably is made up of a plurality
of layers or sheet portions of muslin or percale
sheeting or other suitable material as best shown
in Fig. 2. The lower layer or sheet portion of
this air blanket, designated by the reference character 22, is preferably a sheet similar in size to
an ordinary bed sheet and may be formed out of
similar material which is porous to a certain degree. This sheet extends over the sides and lower
end of the bed.

Open the upper side of the sheet I sew or otherwise suitably fasten a second sheet portion designated by the reference character 23 which may also be made of a similar porous material such as muslin or percale sheeting. This provides an air space between the sheet portion 23 and the sheet 22. In order to prevent the excessive bulging of the sheets when air is supplied to this air space, I connect this sheet and sheet portion by ordinary fabric mesh, screening, or netting designated by reference character 24. This permits the free flow of air through this enclosure and yet prevents excessive bulging of the sheet

On top of the sheet portion 23 I provide a 30 second sheet portion 26 which is fastened to the first sheet portion 23 and the sheet 22 by being sewed therethrough around its edge portions and also by being connected at intermediate points by fabric webbing, netting or screening designated 35 by reference character 27 in a manner similar to the netting or screening designated as 24. This provides a second air enclosure 28 between the top sheet portion 26 and the intermediate sheet portion 23. This top sheet portion 26 may be made of the same material as the other sheet portions but if desired may be made of some impervious material.

At the foot of the bed or some other convenient place I place an air conditioning apparains 10 conclosed in a neat attractive cabinet which may resemble an ordinary night table. This cabinet may either heat or cool the air and supply the air under pressure through flexible tubing 31 to cross duct 34 which distributes the flow of air 50 within the air space or enclosure 25 formed between the lower sheet or sheet portion 22 and the intermediate sheet portion 22. From this enclosure 25 the air which is under a supplied pressure will diffuse through the sheet 22 into the 55 spaces such as the space 32 beneath the air blanket to provide an air conditioned environment surrounding the body of the person sleeping in the bed. Preferably a sufficient supply of air is provided and preferably the air diffuses through the sheet 22 at a sufficient rate so that the air beneath the blanket is of substantially the same temperature as the air which is supplied by the air conditioning apparatus. This will provide an immediate environment of conditioned air surrounding the person sleeping in the bed. The air is also filtered in its diffurion through the

Most of the air which thus diffuses through the sheet 22 into the spaces beneath the air blanket of escapes around the head of the person sleeping in the bed and thus provides conditioned air around the head of the person. If desired, the upper end of the air blanket may be pulled over the nose of the person so that the person will 5 breathe the conditioned air. This is particularly

beneficial to persons afficied with hay-fever and While most of the air which is supplied asthma. to the air space or enclosure 25 diffuses through the sheet 22 into contact with the persons sleeping in the bed, some diffuses through the intermediate sheet portion 23 into the second enclosure or air space 28, thus forming an insulating air space or insulating air pockets. If the top sheet portion 26 is made of a porous material, a slow diffused flow of air is thus provided into 16 and out of the insulating air space 28 thereby carrying away and disposing of any heat leakage from the air in the room so that this insulating air space is maintained at substantially the tem perature of the conditioned air supplied to the 11 air blanket and in this way heat transfer is prevented between the air conditioned enclosure beneath the air blanket and the air in the room since the mattress of the bed provides excellent insulation beneath the person and the air condi- 20 tioned enclosure surrounding the person sleeping. The air blanket may be provided with cross ducts 34 and 35 at the head and foot ends of the blanket as shown in Fig. 3 merely by stopping the mesh or screening 24 and 21 short of the head and the 2: foot ends of the intermediate and top sheet por-tions 23 and 26. The fastening together of the sheet and sheet portion by the mesh or screen portions 24 and 27 provides the air blanket with a pleasing fluted appearance when it is inflated 30 with conditioned air. During the daytime when the apparatus is not in use the air blanket may be covered by a spread as is customary. This air blanket is washable and may be readily washed in the usual manner similar to ordinary bed 31

Referring now more particularly to Fig. 6, for a disclosure of the air conditioning appparatus proper and its application to the air blanket there is illustrated diagrammatically the cabinet 40 having outer walls 36 forming an enclosure which is divided into two parts by a partition 31. Within one of the enclosures 38 formed thereby there is provided a refrigerant compressor 40 divers by an electric motor 48 for compressing apparatus including a refrigerant compressor 41 griven by an electric motor 48 for compressing the refrigerant and forwarding the compressed refrigerant is quefied and collected in a receiver 42. The condenser 41 and the 50 compressor 33 are cooled by a blast of air provided by the fan 43 driven by the electric fan motor 44 and which creates a pressure within the enclosure 38. By discharging or blowing air over the warm condenser, compressor and electric motor, these units of the refrigerating system are cooled and a source of heated air is provided. This heating may be augmented by providing an electric heater 45.

The refrigerant liquefied by the refrigerant 60 condensing apparatus located within the chamber or compartment 38 is conducted through a refrigerant supply conduit 45 into the compartment 48 where a suitable expansion valve or restrictor 48 is provided for controlling the flow of 65 liquid refrigerant through the evaporator 50. Air from the room is drawn through a screened opening 51 into the enclosure 48 by a fan 52 which is driven by an electric fan motor 52 connected in parallel electric circuit relation with the fan motor 44 and the electric compressor motor 40 to a source of electric energy 54. The fan 52 discharges a biast of air over the cold surfaces of the evaporator 50 and creates a pres-

٦.

sure within the enclosure 48 to provide a source of cooled atr

Any suitable form of control means may employed for maintaining the air supplied to the s air blanket at a proper temperature but as a preferred form I provide an air selecting or mix ing device \$0 comprising a pivoted duct arm \$1 communicating with the discharge duct 62 con-necting through the flexible tubing 31 to the air 10 space 25 in the air blanket and capable of selective communication with the enclosures 38 and 48 within the air conditioned cabinet to provide either heated or cooled air or any required mixture thereof in order to provide the proper sup-15 ply of air at a proper temperature and humid-ity to the air space 28 within the air blanket 21. This pivoted duct portion 81 may be automatically moved to its proper selective position by a thermostatic control means which includes a 20 thermostatic builb \$3 charged with a volatile or expansive fluid and located in the air stream of the outlet or discharge duct \$2. This thermostatic builb is a control of the cont static bulb is connected by tubing \$4 to a bellows 65 which operates a lever 68 connected by a link 25 67 to the pivoted selective duct portion 61.

This temperature control me chanism is provided with a selective manual adjustment \$8 comprising spring means and a threaded adjusting means for varying the tension upon the spring 30 means which opposes the expansion of the bellows in varying degrees according to the adjust-ment thereof so as to make it possible to secure almost any desired temperature of gir in the outlet duct 62. However, for ordinary pur-35 poses I find that a temperature of between 75° F. and 85° F. is most suitable. Where the air temperature of the room is either greatly warmer or greatly colder than normal, an additional temperature control may be provided including a thermostatic bulb 70 charged with a volatile or thermal expansive fluid and located within the free air within the room. This thermostatic bulb 19 is connected by tubing 12 to a small metal bellows 13 connected by a multiplying leve 14 and a link 15 to the pivoted duct portion \$1 so as to compensate for the effect of the air temperature of the room upon the heat transfer conditions between the air conditioner space b neath the blanket and the air in the .com. This temperature control may also be provided with an adjustable regulating spring 78 and a threaded adjusting means 11 to regulate the amount of room temperature compensation provided in the selective thermostatic control.

The pivoted duct portion under the control of the temperature regulating apparatus is moved so that its mouth or inlet portion \$1 selectively communicates with the outlet ports 18 and 19 of the air cooling enclosure 48 and the air heating enclosure 38. When the mouth \$1 of the When the mouth \$1 of the pivoted duct portion \$\ i\ is in direct communica-tion with the port 78 the maximum cooling is obtained. In intermediate positions the mouth If of the pivoted duct means I may communicate partly with the port 18 and partly with the port 18 so as to supply a mixture of cooled and heated air to the space 28 of the air blanket. In order to supply warm air, the mouth \$1 may move to a position in direct communication with the port 79 whereby heated air is supplied to the air space 25. If more heating is required. the electric heater 45 is supplied with electric energy by the closing of the switch contacts 82 and \$4, of which the contact \$3 is connected to 75 the link 67 so that when the pivoted duct Lienns

is moved to the extreme heating position, this contact \$3 makes engagement with its cooperating contact \$4 to close the electric heater circuit 45. In this way sufficiently heated air may be provided even when the room temperature is rather cold. rather cold. A permanent magnet \$5 is pro-vided to prevent arcing of the contacts in opening and closing.

The humidity of the cooled air may be controlled by the temperature of the evaporating means 50. The temperature of the evaporating 10 means 50 may be controlled by a manual adjusting means \$6 provided upon the expansion valve 49 so as to control the evaporating temperature witin the evaporator 50 and by this means it is possible to bring the temperature of the air to be cooled below its dew point so as to condense moisture therefrom. This moisture may be coilected in a drip pan \$7 located beneath the evaporator \$0.

Likewise, means may be provided for humidi- 20 fying the warm air when desired by providing a pan 88 containing water which rests upon an electric heater coil 89 connected in parallel electric circuit relation with the electric heater 45. This electric heater 89 evaporates the water at a desired rate in order to supply additional humidity to the air when hot air is required for the air By employing this humidifying apparatus and by suitably regulating the temperature 30 regulating apparatus to obtain the maximum heating of the air, this apparatus may be em-ployed to produce a mild fever in the person in the bed. In order to use the apparatus for producing a fever the adjusting screws 11 and 68 at are actiusted so as to increase the tension upon the loading springs for the beliows \$5 and preferably as far as possible so as to raise the temperature of the air delivered to the bed to 130 or 140° P. The knife switch which controls the energization of the heater 89 is closed and the receptacle 88 is provided with an ample supply of het water. Under such an adjustment the pivoted duct portion \$1 will move to cover the opening 18 and the contacts 83 and 84 will be closed so that the heater 45 as well as the heater 89 will be in operation and by heating the water in the receptacle \$8 and by heating the air the compressing apparatus and the electric heater the temperature of the air and the hu-midity will be raised to a point which will cause a fever. The production of a fever may be aided by having a room temperature in which the apparatus is located as high as possible. The use of artificially created fever has been found very 55 useful in treating certain diseases, and with this apparatus, may conveniently be used as an effective treatment for common colds. Medicinal compounds may also be placed within the pan \$8 to form beneficial vapors. For convenience and 60 clearness, the fans 42 and 52 have been shown as of the propeller type, but because of the higher efficiency I prefer to use the centrifugal type of fan in each case in order to efficiently provide the necessary air pressure for supplying the conditioned air under pressure to the air space 25 of the air blanket 21. The entire apparatus may be controlled by a manual switch \$0.

If desired, other means for heating and cooling

may be employed such as electric heaters, steam, hot water, or hot air from a heating system for providing heated air while ice, solidified carbon dioxide, cold water, or cold air may be employed for providing cold air for my air blanket.

In Pigs. 4 and 5 a modified form of air blanket 75

In this form a full size sheet of musiin or percale sheeting is employed upon the bottom, this being designated by the reference character 100. Sewed to this full size sheet is a second or intermediate smaller sized sheet portion 101 of a similar material which is sewed to the full size sheet 100 around the edges thereof and as shown at 102 and is also sewed longitudinally with the stitching in parallel but which stitching terminates short of the head and foot ends of the sheet portion so as to provide cross manifolds. such as the manifold 103, at the foot and head ends of the air blanket. A third or top sheet portion 184 is likewise sewed to the intermediate sheet portion 181 and the full size sheet 180 by being sewed to the other sheet portions around its edges as shown at 102 in order to provide the second air space or enclosure. The top sheet portion 184 and the intermediate sheet portion ill are connected together to prevent bulging, and to present a fluted appearance, by cords or flah netting #88 extending in a zigzag fashion between the sheet portions and which is sewed or fastened to the intermediate sheet portion at the mid points between the sewed connections 108 by the knotting or stitching 187 and is fastened to the top sheet portion by knotting or stitching 188 which is located at the intermediate points of the cord or netting 188 between the stitchings 181. This form provides an air blanket of an attractive fluted appearance which may be easily

In Pig. 7, I have shown an air blanket type of air conditioning system which provides for the air conditioning system which provides for the recirculation of the cooling air. In this air blanket there is shown a lower full sized sheet 120 to which are fastened, by sewing around the edges thereof, sheet portions 121 and 122 of substantially equal size. These sheets and sheet portions may be made of any suitable material such as a muslin or percale sheeting. These sheet portions are preferably sewed to the full size sheet 126 by sewing or stitching around their edge portions. It should be noted that in this form the upper sheet portions 121 and 122 are shorter than those found in the form shown in Fig. 6. This air blanket has been made in this way so as to prevent the cooling of the feet. It has been found that some persons feel uncomfortable if their feet are cooled as much as the remainder of their body and for this reason the air blanket ahown in Fig. 7 is not provided with the air spaces extending over the feet.

The air blanket 120 shown in longituding) sec-55 tion in Fig. 7 is better shown in Figs. 8, 9 and 10. In this form of air blanket, as stated before, the sheet portions 121 and 122 are sewed to the full size sheet 128 by sewing around the edge portions of the sheet portions 121 and 122. In addition these sheet portions 121 and 122 are sewed to the full size sheet portion 128 along the dotted line 122 shown in Fig. 8 and in Fig. 10 to form a U-shaped return duct 124 in the blanket. The supply duct portions designated by the reference character 125 are formed in the intermediate portions of the air blanket. The air blanket is provided with a distributing air duct 121 located at the lower or foot end of the sheet portions. which duct distributes the incoming air through the fluted supply duct portions 128 through which the air flows until it reaches the outer U-shaped return duct 124 which extends across the head portion of the air blanket as well as along both side portions. The sheet portions 122 and 121 75 are connected together and to the full size sheet

120 by mesh or webbing 128 to form the fluted air blanket structure similar to the first described modification.

Referring now again to Fig. 7, there is shown an air conditioning cabinet or enclosure 130 pro-vided with a dividing wall 131 dividing the enclosure into an air heating compartment 122 containing the refrigerant liquefying apparatus 133 and an air cooling enclosure or compartment 134 containing the refrigerant evaporator 135 which 10 is connected through the wall or partition 131 to the refrigerant liquefying apparatus 133. An electrically driven fan 136 is provided for drawing in air from the room through the screen open-ing 137 and discharging the air over the warm surfaces of the refrigerant liquefying apparatus to heat the air. This heated air may be discharged into the air in the room or into the selective pivoted duct control means [32] through the port 139. An electrically driven fan 141 connected in 20 electrical parallel circuit relation with the motor driven fan 136 and the electrically driven refrigerant liquefying apparatus is provided within the air cooling compartment 134 for drawing air from the room through the screened aperture 25 142 as well as from the return air duct 143 which connects at a plurality of points with the re-turn air duct 124 in the air blanket 120. This air is discharged over the surfaces of the evaporator 135 which cools and dehumidifies the air as re- 30 quired and discharges the air through the outlet port 144 into the pivoted selective duct portion 138 of the discharge duct 145 when required or out into the room when heated air and not cooled air is required for supplying the proper tem- 35 perature of air to the air blanket.

The amount of re-circulation may be controlled by the sliding door 146 which is provided for partially or wholly closing the screened openfor partially or whosis closing the screened open-ing 142 which permits the entrance of air from 40 the room into the cooling compartment 124. The pivoted selective air duct portion 128 has a mouth 148 which is adapted to register with either of the outlet ports 129 or 144, wholly or partially, as required, in order to supply air at 45 the proper temperature to the air blanket. This pivoted duct portion 138 is controlled by 8 charged thermostat bulb 150 located within the air conditioned enclosure beneath the air blanket within the bed and connected by the tubing 151 50 to the metal bellows 182 which through a multiplying lever 153 and a link 154 selectively controls the position of the pivoted duct portion 128 and the connection of its mouth with the outlet ports 139 and 144. Manual adjusting means 155 comprising a spring and adjusting screw acting upon the spring means to control the expansion of the metal bellows 182 is provided for regulating the temperature of the air supplied through the air blanket in order to provide an air conditioned environment according to the desires of the person sleeping beneath the blanket. As in the other embodiments the sheets and sheet portions are preferably made porous so that a considerable amount of air diffuses into the space beneath the 65 air blanket and so provides an air conditioned environment for the person alceping therein while a lesser portion diffuses into the air spaces provided between the intermediate sheet portion 121 and the upper or top sheet portion 122. desired, this form of blanket may be used with the air conditioning system shown in Fig. 6.

In Fig. 11 there is shown an application of my invention to twin beds. In this figure twin beds 180 and 181 are each provided with the air 75

blankets 182 and 183 which may be similar to those illustrated in Pigs. 1 to 6 or similar to that shown in Pig. 12. These air blankets 162 and 163 are supplied with properly conditioned air from an air conditioning unit 154 of ample size which discharges the conditioned air under prescure into an outlet duct #68 which conducts through a common air manifold 166 and 167 to the air blankets 162 and 163.

In Fig. 12 there is shown a longitudinal sec-tion of a bed and air blanket therefor comprising a full size bottom sheet 178 to which is sewed or otherwise suitably fastened an intermediate sheet portion [7] which extends from the head portion of the full size sheet 170 to a point designated by the reference character 172 which is about above the knees of the person sleeping in the bed beneath the blanket. This sheet portion ill is preferably fastened to the full size 20 sheet 118 by being sewed thereto around its edge portions and being connected by knotting, quilting or similar means at intermediate points to prevent the excessive inflation of this intermediate sheet portion 171. The top sheet portion 172, on the contrary, extends from the head portion of the full size sheet 170 to the extreme foot portion thereof so as to provide an air insulating space over the entire body of the person sleeping under the blanket.

Thus in this form the air is supplied from a suitable conditioning means like that shown in Fig. 6 by the supply duct 174 to the air space 175 between the intermediate sheet portion 171 and the full size sheet 170. From this air space 175 the air under pressure diffuses through the sheet 170 into direct contact with the body of the person sleeping thereunder in order to provide air conditioned environment for the body while some of the air diffuses into the air insulating en-(3) closure 116 which forms an insulating air space over the top of the air enclosure 175 as well as the feet of the person sleeping under the air blanket. This form is very comfortable for both winter and summer use

In Fig. 13 there are shown two workmen provided with clothing into which cool air may be supplied from an air conditioning means 180 through a common supply duct 181 and individual supply ducts 182 and 182 under the control of 30 the regulating valves 184 and 185. This clothing in the form of jumpers or air suits 186 and 187 may be made of three sheets or thicknesses of material sewed together so as to provide two air spaces in a manner similar to that of the 55 previously described air blankets. The air is introduced into the air space closest to the body and this air diffuses therefrom in both directions some into contact with the body and some into second air space which forms the air insulating

However, if desired, these suits may be made similar to the sleeping bag shown in Fig. 15 and the air discharged into the interior of the enclosure provided by the air suits and the air per-as mitted to escape therefrom through one or more layers of the material used. Instead of the air conditioning device shown in Fig. 13 these suits may be supplied with compressed air from a com-pressed air line which is ordinarily rather cool 70 and low in relative humidity. I find these suits are suitable for working in hot places such as around furnaces in industrial plants as well as for persons subjected to a cold environment such as those working in icehouses or out in the open 75 For extremely hot situations, the suits should be

made of asbestos or ...imilar fireproof cloth; otherwise, ordinary cloth or fabric goods may be used.

These suits may also be used by aviators for high altitude flights and an apparatus like that shown in Fig. 14 may be used for this put In Pig. 14 there is shown an exhaust pipe 190 of the internal combustion engine used for propel ling the airplane and surrounding this pipe in heat exchange relation therewith is provided water or liquid chamber 191 containing water or other fluid 192 which may be evaporated by the heat supplied by the hot exhaust gases. The evaporated liquid rises into the heat exchange device 193 formed of fins in serpentine tubing through which air is drawn by the electrically driven fan 194 in order to warm the air and this warm air is discharged through the air duct 185 to the air suits. While the air suits 186 and 187 are shown in the form of jumpers they may take any convenient form such as the form of an 20

overcost or other types of clothing.

In Fig. 15 there is shown a bed 200 provided with a sleeping bag 201 capable of receiving a human being and provided with an additional sheet portion 262 providing an insulating air space 25 283 around the top portions of the sleeping bag. The sleeping bag 201 completely surrounds the person therein except for the head thereof and is supplied with conditioned air through the air duct 204 which discharges directly into the interior of the bag 201 at some suitable point in a manner similar to that described for the air cloth-

ing in connection with Fig. 13.

In Fig. 16 there is disclosed a simplified form of control apparatus applicable to either of the forms of air conditioning apparatus illustrated diagrammatically in Figs. 6 and 7. In this simplified form, the enclosure containing the evapor rating means and the cooled air under pressure is designated by the reference character 48b and is provided with an outlet 18b forming part of a butterfly type of double two-way control valve. The enclosure 38b contains the refrigerant liquelying means and warm air under pressure and is provided with an outlet 18b directly opposite the outlet 18b. An outlet \$1b leading to the room is provided for discharging waste air while the dis-charge duct 62b connecting with the air blanket connects to the outlet 82b which is directly opposite the outlet \$1b. A butterfly valve \$2b controis the flow of air from the enclosures 48b and 38b into the discharge duct \$2b and the room outlet according to the temperature requirements.

For this purpose, the butterfly valve \$3b is

provided with an actuating lever arm connected by a link \$5b to a multiplying lever \$5b operated a metal bellows 65b under the control of a manually adjustable spring and screw control mechanism. This believs \$5b is connected by mechanism. This beliews \$5b is connected by tubing to a thermostatic bulb \$3b located within the discharge duct \$25 and charged with a vola-

tile or thermal expansive fluid.

According to the temperature requirements as measured by the thermostatic bulb 63b, the butterfly valve 93b is moved to assume various post- 65 tions. The butterfly valve may be moved to one extreme position to provide a free flow of air from the cooled air or evaporator enclosure 48b to the discharge duct \$2b and from the warm air enclosure 38b directly to the outlet 91b leading directly to the room. When the butterfly valve is moved substantially 90° from this position a free flow of air is provided from the cooled air enclosure to the outlet 91b leading to the 75

room and from the warm air enclosure 18b to the discharge duct \$2b. Under control of the thermostat bulb \$3b the butterfly valve \$3b may be moved to any position from one of these ex-tremes to the other in order that air of the proper temperature may be supplied automatically

Thus, I have provided a personal type of air conditioning equipment which may be used by ersons desiring air conditioning equipment with 10 little or no change of personal habits and which is capable of widespread application and is low

in both initial cost and operating expense.

While the form of embodiment of the invention as herein disclosed, constitutes a preferred form, it is to be understood that other forms might be adopted, all coming within the scope of the claims which follow

What is claimed is as follows:

1. A ventilating means including an inflatable 20 covering for the human body, said covering comprising at least three sheet portions of a flexible material held together to form a plurality of enclosures and means for continuously conducting air under pressure into one of the enclosures between two of the sheet portions to keep the covering inflated and in contact with the body. one of the sheet portions being porous to permit the continuous diffused escape of air therefrom into contact with the body.

2. A ventilating means including an inflatable covering for the human body, said covering comprising at least three sheet portions of a flexible material held together to form a plurality of enclosures and means for continuously conducting air under pressure into one of the enclosures between two of the sheet portions, said two sheet portions being porous to permit the diffused escape of air therefrom into contact with the body

and into another of the enclosures.

3. A conditioning means including air tempering means, an inflatable covering for a human body, said covering comprising a porous flexible sheet means, said air tempering means including means forcing the air through the flexible sheet means into direct contact with the body, said air tempering means including temperature respon-sive means for selecting and providing air of the proper temperature for said flexible sheet means.

4. A conditioning means including air tempering means, an inflatable covering for a human body, said covering comprising a porous fabric sheet means, said air tempering means including means for forcing the air through the fabric sheet means into direct contact with the body. said air tempering means including means for conducting tempered air to the flexible sheet means, and means responsive to the air supplied to the flexible sheet means for controlling the air tempering means.

5. A conditioning means for the human body including body clothing having a plurality of layers of fabric forming a plurality of superimposed air spaces therebetween, and means for supplying air under pressure into one of the air spaces between the layers of fabric, said fabric permitting the diffused discharge of air therefrom into contact with the body.

8. A conditioning means including an inflatable covering for the human body, said covering comprising a plurality of sheet portions of a flexible material held together to form an enclosure, another sheet portion of a flexible material being joined to one of the above mentioned sheet por-75 tions to form a larger enclosure covering a larger

area, and means for introducing air into the first mentioned enclosure.

7. An inflatable article for providing a zone of ventilated air in the vicinity of a body, said article including at least three sheet portions of flexible material positioned one on top of the other and held together to form two enclosures between the sheets located one above the other, said sheet portions having means providing communication between said enclosures, one of said sheet por- 10 tions nearest the body being porous to permit the diffused escape of a fluid from one of the enclo-sures, and means for continuously conducting air under pressure to one of sa'd enclosures, to inflate the enclosures and to provide a diffused discharge 15 of air upon the body.

8. An inflatable article for providing a zone of rentliated air in the vicinity of a body, said article including at least three sheet portions of flexible material positioned one on top of the 20 other and held together to form two enclosures between the sheets located one above the other, said sheet portions having means providing communication between said enclosures, one of said sheet portions nearest the body being porous to 25 permit the diffused escape of a fluid from one of the enclosures, means for connecting dis-persed portions of said sheet portions to limit the distance between the sheets, and means for continuously conducting air under pressure to 30 one of said enclosures, to inflate the enclosures and to provide a diffused discharge of air upon the body.

An inflatable article for providing a zone of ventilated air in the vicinity of a body, said 35 artick including at least three sheet portions of flexible material positioned one on top of the other and held together to form two enclosures between the sheets located one above the other, said sheet portions having means providing com-munication between said enclosures, said sheet portions being quilted to limit the distance between the sheets and to provide a neat tufted appearance, and means for conducting air to one said enclosures.

10. An inflatable article for providing a zone of ventilated air in the vicinity of a body, said article comprising a plurality of sheet portions positioned upon one another and held together to form an enclosure between the sheet portions, 50 means for conditioning air and conducting the conditioned air under pressure to said enclosure between the sheet portions, one of said sheet por-tions nearest the body being porous to provide for the discharge of air from the enclosure into 55 contact with the body, and means responsive to the temperature of the air within said conducting means for controlling said conditioning

11. An infiatable article for providing a zone 60 of ventilated air in the vicinity of a body, said article comprising a plurality of sheet portions positioned upon one another and held together to form an enclosure between the sheet portions, one of said sheet portions nearest the body being 65 of porous fabric to provide for the discharge of air from the enclosure into contact with the body, means for heating and cooling air, mixing means for providing any desired proportion of the heated and cooled air, temperature responsive means 10 for selecting the proper proportion of heated and cooled air, and means for conducting the air selected by the temperature responsive means to said enclosure betw een the sheet portions RICHARD S. GAUGLER.

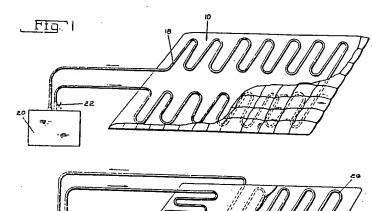
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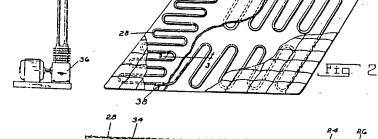
V. W. KLIESRATH

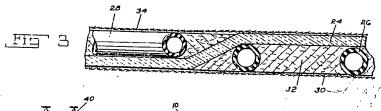
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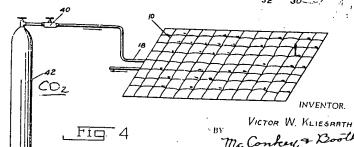
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2 Sheets-Sheet 1









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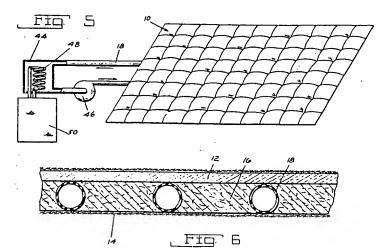
V. W. KLIESRATH

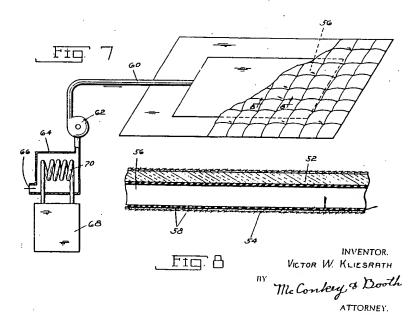
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2,110,022

2 Sheets-Sheet 2





## UNITED STATES PATENT OFFICE

2,110,022

COVER

Victor W. Kliesrath, South Bend, Ind., assignor to International Engineering Corporation, Chi-cago, Ill., a corporation of Illinois

Application July 15, 1935, Serial No. 31,540

3 Claims. (Cl. 5-334)

This invention relates to covers and more particularly to bed covers in which a heat transfer medium is circulated.

It is desirable to be able to control the temperature of a person in bed in order to provide comfortable conditions for sleeping during either extremely hot or extremely cold weather or in the treatment of diseases, for example in hospitals. If the temperature of the whole room is controlled a large volume of air must be conditioned requiring large expensive machinery and leading to high operating costs. It is accordingly one of the objects of the invention to provide a cover by which the temperature of a person in bed may be main-

tained at the desired value without requiring controlling the temperature of a large space. Another object is to provide a cover which is cooled to cool a person using it.

Another object is to provide a cover which is connected to a source of cooling medium to circulate cooling medium through the cover.

According to one desirable arrangement, the above and other objects are produced by a cover including a layer of heat insulating material and a layer of heat conducting material arranged with means therebetween to circulate a heat transfer medium. The heat transfer medium may be a warm fluid or a cooling medium such as a refrigerant supplied by the usual compressor or may be air which is cooled by contact with a cooling In case air is used, it may be circulated through a closed circuit or it may be discharged from the cover to pass over the body of the person using the cover.

Other objects, advantages and novel features will be apparent from the following description when taken in connection with the accompanying

drawings, in which:
Figure 1 is a perspective view with parts broken away of a cover embodying the invention;

Figure 2 is a view similar to Figure 1 of a modifled form of cover;

Figure 3 is a transverse section of the cover of Figure 2:

Figure 4 is a diagrammatic view illustrating a further modification;

Figure 5 is a diagrammatic view illustrating an arrangement in which air is circulated;

Figure 6 is a transverse section through the 50 cover of Figures 1, 4, and 5;

Figure 7 is a view illustrating another modification, and Figure 8 is a transverse section of the cover of

. A.

The cover of Figure 1 is shown as being a guilt

indicated generally at 10 and made up of an upper layer 12 (Figure 6) of heat insulating material such as a wool blanket and a lower layer 14 of heat conducting material such as a relatively thin sheet of cotton linen, silk or the like. The two layers are spaced by a suitable filling ma-terial 15 such as loose cotton and a flexible con-duit 18 of rubber or other suitable material is located in the filling material between the two

The conduit 18 is connected to a refrigerating unit 20 of any desired type and which includes the usual condenser coil and compressing means. Refrigerant under pressure is discharged from the unit 20 through a regulating valve 22 and expands in the conduit 10 absorbing heat therefrom and is returned from the conduit 18 to be recompressed and condensed in the usual menner

Thus the quilt in will be cooled and will cool a person using it without requiring cooling of the 20 entire room. In use, the quilt is placed with the layer 44 of heat conducting material adjacent the body of the user to permit the ready transfer of heat from the user's body to the conduit 18 and with the insulating layer 12 on the out- 25 side to retard the transfer of heat from the outside to the refrigerant

Figures 2 and 3 illustrate a modification of the arrangement of Figure 1 in which both the evaporating cooling coil and the condensing coil 30 are embedded in the quilt. In this modification a heat insulating layer 24 extends along the top of the quilt over that portion in which the cooling coil 26 is embedded and along the bottom of the quilt under that portion in which the condensing 35 coil 28 is embedded. The bottom of the quilt is covered with a sultable beat conducting layer 30 and the spaces between the convolutions of the cooling coil are filled with suitable filling material 32. The upper surface of the quilt over the condensing coil 28 is govered with a cloth cover 34 to permit the transfer of heat from the coil to the atmosphere of the room.

A suitable motor driven compressor 35 has its Inlet connected to the cooling coil 28 and its 45 outlet connected to the condensing coil 28, the two coils being connected by an expansion valve 38. Refrigerant from the cooling coil 26 is compressed in the compressor 36, condensed in the coil 28 and expanded through valve 38 into the 50 cdil 26 to absorb heat therefrom,

Figure 4 illustrates a modified arrangement in which a quilt 10 having a cooling coil 18 identical with that of Figures 1 and 6 is employed. In this arrangement one end of the coil 18 is 55

open to the atmosphere and the other end is connected through a regulating valve 40 with a tank 42 of compressed gas such as CO<sub>2</sub>. Compressed gas from the tank 42 passes through the valve 40 and expands in the coil 18 in quilt 10 to absorb heat therefrom and is then discharged into the atmosphere.

Figure 5 illustrates a further modification employing a quilt 10 having a coil or conduit 18 identical with that of Figures 1, 4, and 6. In this modification the ends of the coil 18 are connected to a box 44 through which air is circulated by a blower 45. A cooling coil 48 is mounted in the box 44 and is connected to be supplied with refrigerant by a refrigerating unit 50 to cool air circulating through the box.

According to this construction cool air only is circulated through the quilt thus reducing the weight of the quilt and eliminating any possibil20 ity of refrigerant escaping from the cooling coil 18.

Figures 7 and 8 illustrate a quilt formed with an upper layer 52 of insulating material and a lower layer 54 of porous heat conducting material with a relatively flat bag 55 of rubber or other flexible material therebetween. The bag 56 is provided with a plurality of openings 58 in its lower surface and with an inlet conduit 60 through which air is forced by a blower 62.

The inlet of the blower 62 is connected to a box 64 having an inlet 66 opening into the atmosphere. A refrigerating unit 68 has an evaporator coil 10 mounted in the box 64 to cool air passing therethrough.

In use of the arrangement of Figures 7 and 8, air drawn into the inlet 66 is cooled by passing over the coil 70 and is forced through the conduit 60 into the bag 56 and out through the openings 58. Thus the cooled air from the bag 56 appasses over the user providing both cooling and ventilation.

While several embodiments of the invention

have been shown and described, it will be apparent that many changes might be made therein and it is not my intention to be limited to any of the forms shown or otherwise than by the terms of the appended dialms.

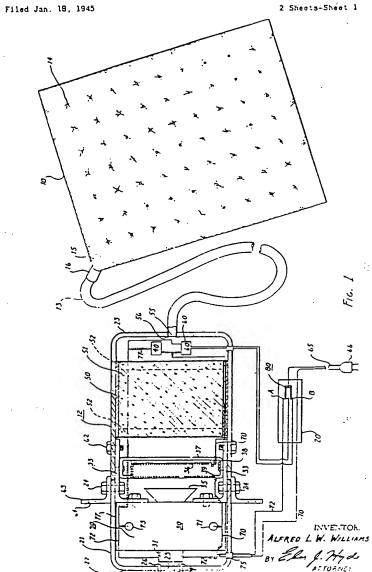
What is claimed is:

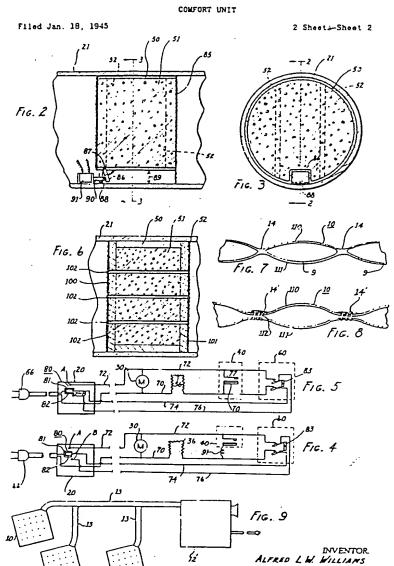
1. A bed cover comprising a layer of heat insulating material, an evaporator coil secured on one side of said material, a condenser coil secured on the other side of said material beside 10 but not overlying said evaporator coil, an expansion valve connecting said coils, and a compressor having its inlet connected to said evaporator coil and its outlet connected to said condenser coil.

2. A cover comprising a layer of heat insulating material, an evaporator coil secured to one side of said layer, a layer of heat transfer material on the other side of said coil from the heat insulating layer, a condenser coil secured to the other side of said heat insulating layer from the evaporator coil, an expansion valve connecting said coils, a layer of heat transfer material on the side of said condenser coil opposite the heat insulating layer, and a compressor having its internance to the evaporator coil and its outlet connected to said condenser coil.

3. A cover comprising a flexible layer of heat insulating material, a flexible rubber tube forming an evaporator coil and secured to one side of said layer, a layer of heat transfer material on the other side of said coil from the heat insulating layer, a flexible tube forming a condenser coil secured to the other side of said heat insulating layer from the evaporator coil, an expansion valve connecting said coils, a layer of heat transfer material on the other side of said condenser coil from the fieat insulating layer, and a compressor having its inlet connected to the evaporator coil and its outlet connected to said condenser coil.

VICTOR W. KLIESRATH.





52

# UNITED STATES PATENT OFFICE

2,512,559

COMFORT UNIT

Alfred L. W. Williams, Cleveland Heights, Ohlo Application January 18, 1945, Serial No. 573,427

22 Claims. (CL 5-347)

1 My invention pertoins to a comfort unit and more particularly to a pad or blanket or the like and an air conditioning unit associated there-with for heating a person or for giving the person a feeling of apparent coolness.

An object of my invention is to provide a com-

fort pad which may be used in bed or the like

for heating a person.

Another object of my invention is to provide a comfort pad which may be used in bed or the 10 like for giving a person a feeling of apparent

A further object of my invention is to provide a comfort pad which will warm a person or which will give the person a feeling of apparent cool- 15 pess

It is also an object of my invention to provide a small, compact, quiet, device for heating and/or apparently cooling a person.

Another object of my invention is to utilize 20

the heating unit in a comfort device for main-taining the "cooling unit" in effective operation. A further object of my invention is to provide

a comfort pad for heating and/or apparently cooling a person which is automatically or semiautomatically controlled in accordance with thermostatic and humidity conditions.

Other objects and a fuller understanding of my invention may be had by referring to the following description and drawLigs, whereir, Figure 1 litutrates partially schematically and

partially in cross-section a comfort unit including a comfort pad and an air conditioning unit.
Figure 2 is a sectional view along lines 2-2

of Figure 3, showing a modified form of a por-tion of the air conditioning unit which may be used with the comfort pad shown in Figure 1.
Figure 3 is a sectional view along line 2.

Figure 4 is a circuit diagram of the modified form of my invention shown in Figures 2 and 3. Figure 5 is a circuit diagram of the form of my

invention shown in Figure 1. Figure 6 illustrates a further modified form of my invention.

Pigures 7 and 8 are enlarged cross-sectional views of portions of two types of comfort pads which may be used in my invention, and

Pigure 9 schematically illustrates a multiple installation utilizing my invention.

With respect to Figure 1, the invention com-prises a pad or blanket unit 10 which is connected to an air conditioning unit, indicated generally

The comfort ped or blanket unit 10 may comprise any material through which a small amount of previously conditioned air may be caused to flow. And it may be positioned near a person so that the conditioned air which flows out of it will come into contact with the body of a person; or the comfort pad 10 may be a mat-tress or pillow upon which a person may lle. I prefer to utilize a pad comprised of two sheets of substantially air impervious material:

sneed of substantially air impervious material; there two sheets being connected together at their edges and at a plurality of spots 14 throughout their area as is shown in Figure 7. One sheet of this pad has a plurality of small holes, such as pin holes S in it, through which the con-

ditioned air furnished to the pad passes.

The material from which the pad 10 is made is relatively immaterial so far as my system is concerned. However, I prefer to utilize "Koro-seal" sheets, as the material is very pliable, is air impervious except where small pin holes are made, and does not mistle when it is bent and made, and does not ristle when it is cent and crimped. This lack of rustle is of advantage when my pad is used by a sleeping person as 25 occasional turning and tossing about will not cause noise by wake the person up. Further, when a material such as "Koroseal" is utilized the connections 14 and the edge seal between the upper and lower layers may be made by momentarily applying an amount of heat sufficient to slightly melt the "Koroseal" while simultaneously or immediately thereafter applying pressure while the spot cools to cause the two layers to "weld" together. This may be called "spot welding" as the two sheets become integral at the edges at the spot 14. It is also within the scope of my invention to sew the two layers together either in spots or in long lines, and to seal the needle holes in one of the layers by means of any hard-enable sealing material but leaving the needle holes in the other layer for the air to escape as shown by Plaure 8.

The hose 13 may be connected to one corner of the pad 10 by any suitable means such as the flat funcel 15 which may be comprised of plastic. metal, or the like, and which extends inside the corper of the pad. One end of the hose 13 may slip in the tube-like portion 16 which is integral with funnel 15 and may be suitably connected thereto by clamping or gluing or by friction. Air which is blown through the hose 13 thereby enters the interior of the pad 10 and due to the slight amount of pressure which is built up by by the reference character 12, by means of a ... the resistance of the air to passing out through hollow air impervious tube 13 of suitable length. as the small pin holes in the pad a slight belicon

action or puffing of the pad is obtained. The plurality of points 14 where the two sheets comprising the had are connected to ether prevent the pad from becoming too thick when it pulls up. The slight pressure, say, for instance, 1 to 2 ounces, is sufficient to cause a flow of air through the numerous pin holes 9 in one side of the pad. Thus If the pad is threwn over a person with the pin-hole side down the air which flows out of the pad comes in contact with the person's 10

body.

The pad 10 may be the size of a blanket so that it can be tucked in around the mattress, or it may comprise the center section of a composite blanket the edges of which are of ordinary blanket material and adapted to tuck in around the mattress. The center section of the com-posite blanket would comprise the pad portion 10 which thereby is adapted to be positioned over that portion of a bed normally occupied by a person. Also, the pad may be small and adapted for insertion : nder the covers of a regular bed to that it would not need to be : licked in. It is also within the scope of my invention that the tube 13 may be connected to a mattress and the mattress may be air pervious or may have a plurality of holes by means of which the air could come in contact with the body of a person lying in bed.

Connected to the end of the hose 13 opposite 30 the blanket end is an air conditioning unit in-dicated generally by the reference character 12, and a switching mechanism indicated generally by the reference character 20 is provided for controlling the air conditioning unit. Details of this 25 switching mechanism 20 will be more fully described later.

The air conditioning unit 12 comprises a hollow tubular member or housing 21 which may be cylindrical or oval or any other shape in cross-section, and the member may be formed of metal. plastic, or spirally wound paper the successive windings of which are connected to each other by glue or plastic material to form a hard, rigid tubular member. This housing 21 has two end portions 22 and 23, integral respectively with two side wall portions. This construction facilitates assembly but it is to be understood that the housing 21 may comprise a single ; lece tubular memer and the end portions 22, 23 may be connected thereto in any suitable manner. Through the end 22 there is an air inlet opening 23 having grill work 24 such as a plure lity of finely spaced bars and/or a layer of cloth or the like for preventing the ingress of foreign matter into the housing 21. The grill 24 may be snapped into the housing and maintained there by means of spring lugs

26 or by any other suitable means.
Within the housing 21 and just inside the opening 23 there is positioned an air pump 30 having an opening 31 positioned closely adjacent the air inlet 23 into the housing 21. The air pump 33 is mounted on the wall of the housing 21 by means of angle irons 33 and nut and bolt devices 24, and comprises an electrically driven motor for driving an air impeller which may be any suitable type which delivers on the order of 5 to 10 cubic feet of air a minute at a pressure of about 1 or 2 ounces. The electric mutor and pump should be sufficiently quiet in their operation that a person trying to sleep would not be disturbed either by noise or by vibrations. The air pump unit 30 has an outlet 35 from which the air is blown against a heated such as an elec-

resistance wire is mounted on the same angle from 13 by means of a bar 31 of insulating material: the bar 37 being secured to the angle from 32 by screws 21 or the like. A convenient method for connecting the resistance wire 36 to insulating member 37 is to through it through holes 33 through the inwardly turned leg portions thereof.

Within the housing 21 there is a container \$0 which may be comprised of light cariboard, heavy paper, metal, plastic or the like. The container is shaped to fit within the housing 21 tainer is shaped to fit within the nousing at with its wall portions snugly against the interior surface of the housing, and it has air pervices and closure means such as cloth stretched across the ends and connected "he walls of the container so. Within the container so is a large amount of silicage! Si or other moisture absenting means. The cloth end closures prevent this ing means. The cloth end closures prevent this silica gel 51 from spilling out of the container \$0 into the housing 21 yet permit the air which flows through the container to pass through the container 80.

The end 23 of the housing 21 has an outlet opening 55 to which is connected one end of the hose 13. Any means may be utilized for connecting the hose at this outlet opening such as a number of spring clips 56. Mounted on the wall of the housing 21 preferably between the silics. gel container 50 and the outlet opening 55 is a hygr. tat 60 and a thermostat 40. These are scheme lically shown as a wide variety of com-merically available hygrostats and thermostats may be utilized to control my air conditioning unit.

The angle from 33 may be utilized for securing the two portions of the housing together. The bolt arrangement 24 secures one end or the housing 21 and a bolt arrangement 62 secures the other end of the housing to the angle iron 33. One or more externally mounted angle from 63 may be connected to the housing 21 and to the internally mounted angle iron 33 by means of bolts 24, and each angle iron 63 may have a mounting hole 64 through it whereby the conditioning unit may be connected to the frame of a bed. Other suitable arrangements for connecting the air conditioning unit 12 to a bed may be utilized, such as by swinging it in a hammock which is suspended from the bed. This will pre-vent vibration from being transmitted from the air conditioning unit to the frame of the bed. Also, any of the well known rubber mounting devices may be utilized to reduce the transmission of vibration to a bed.

The control panel 20 may be mounted on the head or on the side of the bed or, if desired, it may be a separate movable switch which may be positioned on a night table beside the bed. Connected to the control panel 20 is an electric cord 65 which may be plugged into any convenient source of electric power, such, for example, as a 110 v. 60 cycle, A. C. supply, by means of a plug 55. One side 10 of the electrical supply line may go to terminal 71 of the air pumpunit 30 and the other side 12 of the supply line may be connected to terminal 13 of the air pump unit 30. The wires 10 and 12 extend through the housing 21 by means of a small hole drilled therein and this hole may be sealed by a grom-met 75. The electric motor in the air pump unit 30 is in parallel with the electric heater coil 15, and the electrical circuit through the heater coil the air is blown against a heated such as an elec-trically energized coli of resistance wire 36. The 75 (see Figure 5) of the thermostat 40. The other

side of the motor circuit is connected to the thermostat 40 by means of wire 11. The ther-mostat 40 is arranged so that it opens the cir-

cuts through the heater 18 when it is satisfied.

The hygrostat 60 is in parallel with the thermostat 40 and independently of the thermostat 40 supplies actuating current to the electric motor in the air pump unit 10 for starting the pump, and at the same time completes a circuit through the heater coll 15. These functions are performed when the humidity within the ho. sing 12 is high.

In the winter the air conditioning system opcrates as follow:

The thermostat 40, which may be manually 15 adjustable over a wider range of temperatures. may be set to any temperature for keeping a person comfortable. The comfort pad 10 is thrown over a person either by itself or with blankets on top of it. The operator throws the 20 switch \$8 on the control panel 20 into position A: Power is thus supplied to the electrical driving unit in the air pump 39 which sucks in air through the opening 23 and blows it by means tube 13 into the comfort pad 10 and from 25 there it flows around a person's tody. The thermostat 40, not being satisfied by the cool air which is being taken in at the inlet 23, establishes an electrical circuit through the heater 38 and the air which is blown out of pump outlet 35 is heated. This air passes through the silica gel 51 thereby heating the silica gel, and the warm air passes through tube 13 which may be heat insulated, into the comfort pad 10 from where it passes out of the small pin holes 9 and into contact with the body of the person Upon the thermostat 40 becoming satisfied by the heat supplied by the coll 36 it opens circuit which breaks the current supply to the coil 36 thereby shutting off the heat. The air which is blown through the silica gel 51 after the The sir heater has been turned off, is slightly warmed due to the heat that is stored in the siling gel but soon the thermostat will no longer be satis-fled and will close the coil energizing circuit thereby supplying current to the heater 35

While I have shown a heater device which is operated by a make-and-break thermostat it is also to be understood that it is within the scope of my invention to utilize a heater device which does not continually turn on and off but which supplies a relatively constant amount of heat and the thermostat operates to adjust the amount from zero to a large amount. The hygrostat 80 is not escential for the winter opera tion as large amounts of heat may be imparted to the air which is blown around the person thus making the person feel warm regardless of the moisture content of the air.

It is well known that the comfort of a person depends upon several factors, among them being the temperature of the air, the humidity of the air, and the motion or velocity of the air surrounding the person. Thus, an amount of surrounding the person. Thus, an amount of warm dry air having sufficient velocity will give a person the feeling of apparent coolness if it evaporates moisture from the skin of the person. It is this evaporation which makes the person apparently feel cool. In the winter warm dry air, If it evaporates moisture from the skin of a person, might make that person feel cool whereas warm moist air would make him feel warm. the device shown in Figure 1 dry air is supplied

becomes immaterial. The device shown in Fig. ures 2 and 3, which is to be described in detail later, provides for supplying to a person worm air which has not been dehydrated and thus not as much heat need be imported to the air.

In the summer when the air is warm and its moisture content is high, the device would ourate as follows: The silica gel is drs. When the switch blade 80 is in position A the blower 30 is operating. Heater coll 35 is not energized as the temperature of the warm moist incoming air satisfies the thermostat 40 and its contacts are open to break the circuit through the coil. ostat 60 is satisfied because the silica co. being unsaturated, maintrins the air within the container at a low moisture content. Thus its electrical circuit is broken. The warm moist air is forced through the silica gel container 50 where substantially all of its moisture is removed, and this dry air is blown onto the person in bed thereby making him feel cool due to the evaporation of the body moisture. Sufficient silica gel 51 is in the housing 21 for a number of hours of operation, such, for example, as hours. This means that there must be sufficient silica gel to absorb the moisture from the sir which passes through the container in ten hours of operation. Thus the volume of hir which is blown about a person should be kept to a minimum. For this reason I provide pin heles only on the bottom layer of the material which comprises the pad 10.

After the device has been in operation all night the moisture which has been absorbed by the silica gel must be driven off in order to prepare the silica gel for the next night's operation. Thus upon rising in the morning switch binde 80 is thrown into position B, where blade 81 establishes a circuit through wire 74, through switch 83 (when hygrostat switch is closed), and through the heater 36. Blade 82 establishes a circuit through wire 76, through switch 83 (when hygrostat switch is closed), and through wire 72 to energize the blower 30. The hygrostat switch will be closed due to the saturation or near saturation of the silica gel and thus the heater and blower will both be on regardless of the position of the thermostat switch 40, and hot air will be blown through the slitcat gel 51 thereby taking substantially all of the moisture out of the silica gel. When the silicat gel 51 has become sufficiently dry or re-activated the air which is blown about the hygrostat 60 will become dry and the hygrostat will open the circuit B through the motor and through the heater thereby automatically shutting both of them off

If the moisture content of the air which has been passing through the air conditioner during a night operation is not high enough to saturate the silica gel, then throwing switch biade 80 into position B will not cause the motor 30 and the heater 36 to be energized. The next night when the person wishes to retire, he throws switch ad from position B into position A. This starts the electric motor which operates the electric blower to cause air to be blown through the silica gel 51 into the comfort pad 10. Due to the fact that the silica gel has either been re-activated or has not needed re-activation, the air which passes around the hygrostat will be relatively dry and will not cause the hyprostat 60 to try to establish a con-However, should the silica gul become satto the person. However, sufficient heat may be urated due to long continued use without the op-imparted to that air that the dryness thereo? 75 erator throwing the switch 80 into position B no

harm will be done by the closing of the hygrostat

ontacts as circuit B is open at the switch 80.

Pigures 2, 3, and a illustrate another form of my device. The silica gel unit 85 extends only part way across the housing 21. The remainder of the distance is closed by a fize arrangement 86 which is pivoted at 81 and which may seal against the abutment 88 for substantially pre-venting air from flowing through the passageway 89. The flap 88 is under the control of a solenoid operated plunger 90 and the coil 91 of the solenoid operated plunger is arranged in the electrical circuit of the thermostat 40 as shown in the circuit diagram of Figure 4 so that when the thermostat 40 is not satisfied and is calling for heat the flap 85 is open allowing air to pass through the passage-way 89. Accordingly, in the winter time when heated air is being supplied to the comfort pad 10 substantially all of the air by-passes the silica gel and retains its moisture. 20 Thus warm moist air is supplied to the person in bed rather than warm dry air, and it has been found that the amount of heat supplied to the air by the heater coll 36 in order that the person should feel a given degree of comfort is con- 25 siderably less.

Silica gel and many of the other dehydrating agents have the characteristic of absorbing sub-stantially all of the moisture in the air which passes through it until the silica gel reaches sat- 30 uration, at which point the agent no longer sorbs any moisture. In other words, the silica gel, while active, takes substantially all of the moisture out of air. It is not always desirable or necessary to pass absolutely dry air around the 35 body of the person in order to give him a feeling of comfort, and during very moist days the of operation would be large, therefore requiring a large amount of silica gel in the housing with consequent higher pressure to force the air through the silica gel container. If, for instance, the atmosphere has 89% humidity and air of 40% humidity is blown about a person he will feel more comfortable. Accordingly, only a portion of the moisture in the air need be removed, thereby saving in silica gel and saving on the size of the unit.

Figure 6 illustrates a modified form of silica gel container for passing air to the comfort pad which is not substantially 100% dry. It com-prises the container 50 having end closure means 52 similar to the end closure means in Fi At the ends it has rigid supports 100 and 101 over which the cloth to retain the silica gel is stretched and to which it may be connected. Between these two supports extend a number of small air pipes 102. The silica gel 51 is positioned around these pipes and the air which passes through the pipes does not become dehydrated as it does not contact the silica gel. The pipes 102 preferably should be of such size and number that there is established a resistance to the flow of air therethrough which approximates the resistance to the flow through the silica gel. If the pipes were too large too much of the air would pass through them and not enough through the silica gel, re-sulting in insufficient dehydration of the air. If the resistance to the flow of air through the pipes 102 approximately equals the resistance to the flow of air through the silica gel then about one half of the air will pass through the silica gel and half will pass through the pipes. On a day which has, for example, 80% humidity, the hu-

This is a sufficient drop to will be about 40%. be readily noticeable by a person and would give

an apparent feeling of coolness.

It is within the scope of my invention that moisture can be added to the air which is de-livered through the comfort pad 12. This would be particularly valuable during dry winter nights. One method of adding moisture to the air would be to provide an opening in the top of the silica gel container 50 through which a small amount of water could be poured. The silica gel 51 will absorb this water and as warm air is forced through it, it will give the moisture up. methods which could be used would be to pro-vide a tank of water with a wick of air pervious cloth or the like partially immerced in the water. Obviously a number of other methods could be

The comfort pad 10 has been described as comprising two sheets of material connected together at their edges and at a plurality of spots throughout its area to establish a hollow pad which does not "balloon" up when air under pressure is supplied to the pad.

plied to the pad.

Figures 7 and 8 illustrate two methods of connecting the two sheets [10 and 111 together. In Figure 7 the sheets have been "spot welded" together by applying to localized spots sufficient heat to soften the material and while the material cools pressure is applied. At the spot 14 the two sneets 110, 111 fuse together and become integral. Between the sheets at areas where they are not connected together the air is free to flow.

In Figure 8 the two sheets 110, 111 have been stitched together with thread 112, and the needle holes in the sheet 110 have been sealed by means of a hardenable material such as plastic cement, glue, shellac or the like to prevent air from es-caping. The needle holes in the sheet if i remain open for air to escape, thereby obviating the necessity for special air holes 9.

Figure 9 illustrates a multiple installation utilizing a plurality of comfort pads 10 connected to a single air conditioning unit 12' which obviously may be of a larger size than that used for a single pad. It is contemplated that hotels could have a central condition unit and pipes leading to all of the rooms. To these pipes the comfort pad shown in Figure 1 could be connected. In an installation of this size it would be economical to actually cool the air which is delivered.

While I have described my invention with a certain degree of particularity it is to be understood that numerous other arrangements of parts and many other different materials and processes of manufacture may be used without departing from my invention.

I claim as my invention:

1. In a comfort unit; the combination including enclosure means having a plurality of small holes therethrough and adapted to be positioned near a person; hose means one end of which is connected to said enclosure means; air conditioning means connected to the other end of said hose means, said air conditioning means including means for dehumidifying air; and means for forc-ing air through said dehumidifying means for dehumidifying said air and through said hose into said enclosure means from where it passes through the holes therein into contact with the body of the said person for establishing a cooling

2. In a comfort unit; the combination including enclosure means having a plurality of small midity of the conditioned air of the comfort pad 75 holes therethrough and adapted to be positioned

15. In a comfort pad as described, a plurality of thin cheeks of thermoplastic material disposed in face-to-face relationship and integrally connected together at a plurality of discrete locations throughout its area and connected integral ions inroughout its area and connected integrally together in a continuous line about the peripheral edge thereof, said pad having an air inlet opening communicating with the space between said sheets and having a plurality of smaller air outlet openings, the said plurality of air outlet 10 constants being in advanced and about openings being in only one of said sheets.

11

18. An air conditioning device as set forth in claim 15, further characterized in that said means for conditioning the air comprises a chemical dehydrator adapted to attract and hold 15

17. In a comfort unit; the combination including a flexible pad defining an enclosure having a plurality of small holes therethrough and adapted to be positioned near a person; air conditioning means connected to said flexible pad which passes through said housing passes through said which passes through said housing passes through said moisture absorbing means. and including a supply of a chemical dehydrator adapted to attract and hold moisture, and means for forcing air into contact with said chemical dehydrator for at least partially dehumidifying 25 said air and thence into said pad from where it passes through said holes into contact with the body of the said person for establishing a cooling

18. In a comfort unit; the combination includ- 30 ing enclosure means having a plurality of small holes therethrough and adapted to be positioned near a person, a housing having an air inlet open ing and an air outlet opening connected to said enclosure means, blower means for forcing air through said housing, moisture absorbing means within said housing for absorbing moisture from said air which is blown through said housing. means for heating the air which is blown through said housing, thermostat means for regulating the heating of said air, a hygrostat within said housing, electrical circuit means connected through said hygrostat to said blower and to said heater means, and switch means having a first and a second position, said switch means in said first switch position controlling said electrical circuit means to cause said blower and said heater means to operate together to blow warm air through said moisture absorbing means and out through said housing outlet independent of

the position of said hygrostat, and in said second switch position controlling said electrical circuit means to cause said blower and said heater means to operate together only when the humidity with-in said housing satisfies said hygrostat to close the electrical circuit therethrough, said thermo-stat being operable when said switch means is in said first position to reduce the heat supplied by said heater means.

12

19. A comfort unit as set forth in claim 18, further characterized in this: that said thermostat means is adjustable to regulate the heat supplied by said heater means.

20. A comfort unit as set forth in claim 18, further characterized in this: that said moisture absorbing means comprises silica gel through which the air blown through said housing must

which passes through said housing passes through said moisture absorbing means.

22. A comfort unit as set forth in claim 18, further characterized in this: that only part of the air which passes through said housing passes through said moisture absorbing means.
ALFRED L. W. WILLIAMS.

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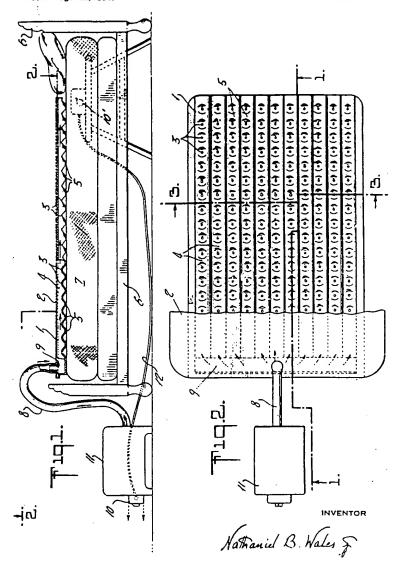
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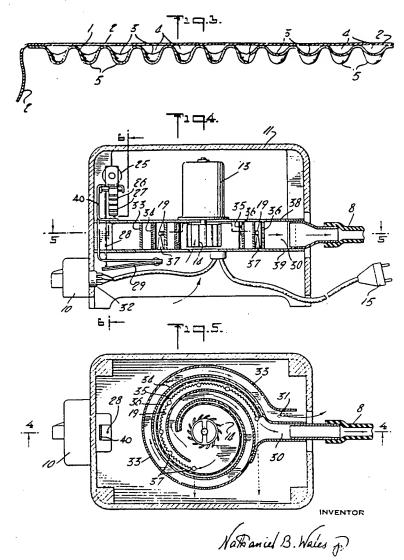
N. B. WALES, JR

2,601,189

AIR COMFORTER FED COVERING

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3 Sheets-Sheet 2



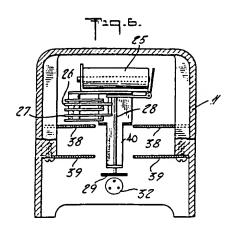
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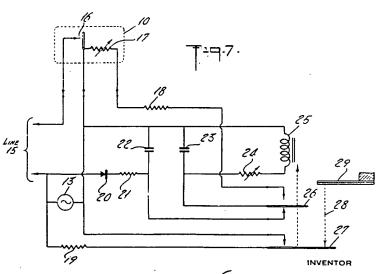
N. B. WALES, JR

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#### STATES PATENT **OFFICE** UNITED

AIR COMFORTER BED COVERING

Nathaniel B. Wales, Jr., New York, N. Y., as-signor to Theodore Backer, New York, N. Y.

Application August 22, 1949, Serial No. 111,647

6 Claims. (Cl. 4-160)

This invention relates to a device for deliver-ing fresh or tempered air to the sleeping human body, and to automatic means for providing and regulating such tempered delivery of air.

by means of a program of research in the prior art of air conditioning beds, and of experimentation with such devices. It has been found that the inflatable type of bed covering or air delivery de-vice, which appears in the erior art, suffers from two practical difficulties which have prevented such devices heretofore from being offered on the market. The first of these objectionable features is that in order to maintain distribution channels is that in order to maintain distribution channels by inflation, an appreciable air pressure is neces-sary. This may be provided either by a highly 15 constricted system of delivery apertures, such as that provided by an infrequently perforated inflatable duct using a moderate volume of air delivery, or by a minimized constriction system, such as that offered by a highly perforate inflatable sheeting requiring a correspondingly large nble sheeting requiring a corresponding large rate of air volume delivery, to maintain inflation pressure. The first case results in the delivery to the body of many high velocity minute jets of air with a consequently unhealthful and uncomfort-nble localized chilling action, whereas this second case, involving both high pressure and high volume of delivery, necessarily requires an excessive amount of blower power, and in addition introduces difficult noise problems, since this class of 30 device must be virtually noiseless.

The second objectionable characteristic of the

inflatable type of covering has been found to be its formation of "hot spots" where it contacts the body due to its natural tendency to conform to the 35 body. At these areas of contact, circulation of the air is inhibited, and the consequent tempera-

ture gradients are uncomfortable.

The present invention obviates these difficulties In the present invention doviates these difficulties by its concept of the combination in a bed cover- 40 ing, of a flexible self-sustaining non-infiated duct delivery manifold with a grid of closely spaced support points on its underside to provide homogeneous accessibility to the covered body of the delivered air.

Because of the fact that this labyrinth of distribution ducts is self-sustaining, although light and flexible, it requires only a fraction of the air delivery pressure which an inflatable duct would require. This permits the use of a small low 60 powered blower unit to diffuse the tempered air at low pressure uniformly over the body, since the duct structure taught by this invention combines self-sustaining air delivery channels with flexi-bility, light weight, and a geometry guaranteeina an absence of air-obscured areas on the sleeper.

It has been found that this self-sustaining flex-ible distribution labyrinth may be formed by subjecting a thin sponge composition sheet, such as of foam rubber or plastic, to pressure under appropriate temperatures in a roll press or molding die. The desired geometry provides longitudinal self-sustaining air channels with a grid of supporting fingers or bumps directed downward so as to prevent any appreciable area of the body on which it may bear, either directly or through an interventing shear, from belong made inappreciable and inappreciable area.

which it may bear, either thready of indecessible intervening sheet, from being made inaccessible of the air delivery to the covering.

In a preferred form of this flexible air delivery manifold, the formed sponge rubber or plastic covering above described is perforated at interval: along the air delivery channels in such a way as to insure uniform air delivery over the area of the covering, and a thin flexible air-impervious sheet is secured to the top of the corrugated sponge composition air channels to comprise self-sur-taining air ducts. Thus, in this preferred form of dry air comforter, the upper wall of the ducts? formed by the air impervious sheet, while the lower walls of the ducts are formed by the molecular sponge composition under-covering. This com-posite manifold may be fabricated in such a way as to be extremely light and flexible.

Evidently, the flexible self-sustaining manifold

principle embodying my concept of a grid of sup-port points may be fabricated in a variety of ways and with various materials, such as by an extrusion wholly containing the self-supporting of ducts made of a plastic feam. A second alterna-tive execution of this combination may be effected by joining one imperforate spect at a grid of points with a perforate spect by means of multiple closely positioned spacers so as to provide the self-sustaining duct feature in combinating with multiple under surface support points.

It is further possible for this purpose to secure

a plurality of mutually interconnected redividual perforated tubular ducts to a fixable laminar backing sheet to achieve the same and of soilsustaining flexible air delivery ducting having of dispersed support geometry.

The air comforter embodied in this invention is intended to provide sleeping comfort all year round. To attain this, it has been recognized that the principal source of discomfort in hot weather is the humidity, rather than the temperature, since an excessive humidity causes the human body's natural refrigeration mechanism of surface evaporation of its perspiration, to become inopevaporation of its perspiration, to decembe map-erative due to the opposing vapor pressure of the air. This invention teaches the use of a draining agent, such as silica-sol to particily remove the moisture from the air delivered to this due to bed covering. Since such drying agent, are con-crally exothermic in action, this invention four teach discloses a heat interchanging structure which utilizes a portion of the air delivered by the blower to reduce the temperature of the air thus dried

and heated to a temperature closer to the ambient term temperature, thereby providing a further natural and healthful source of body refrinera-

The air delivery unit shown in this invention is provided with air heating means, for winter use, regulated by a novel form of thermo-tatically responsive control device. In addition, a separable manual control box is disclosed to con-structed that after the initial period of personal adjustment has been passed, the control box, to-wether with its registration of personal selection thus established within it, may be disconnected from its cable, and plugged directly into the air delivery unit, thereby obviating further inconvenience due to the presence of this cable.

An object of this invention is to provide a structure of air-distributing bed covering which will not be contingent on air pressure or the sleeper's movement or position to insure uniform diffusion 20 of air over the area of the bed.

A second object is to make possible the health-ful comfort of a sleeper in hot weather without the use of chilled air.

A third object is to make possible the manu- 25 facture of an automatic year round air comforter hed covering at a minimum of cost, and at a maximum of quiet and comfort

Other objects are implicit in the following specification and claims.

Referring to the drawings: Figure 1 is a view in elevation of a bed showing the disposition of the air delivery and tem-pering unit, the separable manual control box. view in section of the preferred form of iny self-sustaining air delivery manifold.

Figure 2 is the plan view of Figure 1 showing the bed covering in partial section along the

Figure 3 is the section of 3—3 of Figure 1.
Figure 4 is a section in elevation of the air delivery unit 1—1 of Figure 1.

Figure 5 is the plan section 5-5 of Figure 4. Figure 6 is the section 6—6 of Figure 4; and Figure 7 is a schematic wiring diagram of the control system of a preferred form of my invention.

The bed covering detailed in Figures 1, 2 and consists of an upper flexible air-impervious chect 2 which is secured to the periphery and to the longitudinal lines of contact which it makes with the under flexible corrugated and pre-formed duct member 1. The means of this securance may comprise cementing, riveting, sewing, or, in the case of plastic materials, thermal honding. The duct member i may be made of aponge rubber or of plastic foam. It is provided with a system of perforations 3, and is so formed as to present a grid of support protuberances 5 on its under side. The longitudinal duct passages 4 are formed in the space between the upper impervious sheet 2 and the longitudinal corrugations formed in member 1. It may be ceen in Figure 3 that the protuberances 5 depend from the duct passages 4 and that the air delivery holes 3 are located in the less protuberant lower boundaries of the ducts so as to per-mit free diffusion of the delivered air over the sleeping body covered by this perforate member As essential feature of this construction is its provision of an air delivery manifold which need not be inflated to form its passages. Thus the self-sustaining nature of these passages will not be closed off or strangled by the creasing. folding, and bodily obstructions, such as by the 75

weight of an arm or les, which is ruffered by any ducting system dependent on air greating inflation

The longitudinal air delivery ducts 4 are shown in Figures 1 and 2 all to communicate with the common transverse manifold duct 9 at the foot of the bed covering. Distribution that In turn is connected by the Serible coupling duct 8 through a suitable separable connector. Duct 8 provides the means for delivery of tempered air from the blower unit 11 to the bed covering, shown resting on the bedding I of bed 6. In Figure 1 the separable manual control box 10 is shown in full line plugged into the blower unit 11. The broken line outline 10 shows this control box in its alternative bedside position when connected to the blower unit through cable 12. As shown at the left at Figure 3 the upper impervious sheet 2 is provided with sufficient excess area beyond its securance to duct member I to form a skirt which hangs over the edge of the bed, or may be tucked in under bedding 7, so as to confine the entrance of air underneath the bed covering to the tempered air delivered at low pressure by the blower unit II

The blower and tempering unit shown in Figures 4, 5 and 6, comprises a case 11 sustaining an upper (preferably metal) chassis plate 33 and a lower chassis plate 39. These are spaced apart by and secured to the spiral sheet metal walls 33 and 34 so as to form a main air delivery and drying duct 30, and a heat exchanger duct 31. A blower rotor 44 is positioned at the center of the duct system and is driven by motor 13 secured to upper chassis plate 35. Air en-ters blower rotor 14 axially through the circu-lar hele in lower chassis plate 39, and is delivered in major part through spiral duct channel 30, thence entering delivery tube 8 for distribution through the bel covering. A smaller portion of the nir is passed through duct 31 where it cools the wall 34 thence passing out into the room via the clearance hole in case 11 sur-rounding exit duct 8. Channel 30 is provided with a chemical drying agent 35 for absorbing moisture from the air passing through this channel. This agent, such as silica-gel, may be of granular form, and is contained between a close meshed screen 35 and the duct wall 34 no has to present a large exposed area to the air passing through duct 30. In addition, due to the spiral geometry, the centrifugal component of the air's motion tends to assure a thorough contact between the air and drying agent so positioned. As before noted the absorption of moisture is accompanied in most drying agents by an exothermic reaction which would tend to heat the agent 36 and with it the delivered air. However, an appreciable portion of the heat so generated is conducted through the wall 34. which is in intimate thermal contact with the drying agent, and this heat is carried off by the portion of the air blast delivered by the blower through duct 31. This results in an utimate net refrigerative effect on the person to mate net retrigerative effect on the person to whom the nir-is delivered. An electric nir heat-ling element 19 is positioned in duct 30 and in supported on stand off insulators 31 secured to the lower plate 39. This heater wire 19 is energized periodically in cold weather at a rate and pulse length of which the integrated power dissipation is made to be a function of the room's ambient temperature at measured in his room's ambient temperature as measured by bimetallic thermoresponsive element 29. It is evi-

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dent that by switch means obvious to the art, heater 19 may be continuously energized for a period during the day so as to recencrate the drying agent 36 by baking out the moisture absorbed during the hight. Bimetallic element 25 is mounted on a bracket 46 secured to upper chassis 38, the relay 25 carrying leaf switches 28 and 27 is also incounted on bracket 40. A push rod 28 so connects the end of bimetallic real 25 and the armature of relay 25 that the resiliency of leaf 29 and the force generated by thermal stresses therein causes this leaf so act as the bias spring for the armature of relay 25. This thermally variable mechanical bias on redent that by switch means obvious to the art, This thermally variable mechanical bias on relay 25 is utilized to control the effective dissipation of heater 19 as may be seen with reference to Figure 7. In Figure 7 a master control switch is, located in the separable box io. applies the line current from terminals 15 to the blower 13 and to the heater element 19 through normally open relay contacts 21. In addition, this line voltage is rectified by dry rectifier 20 and applied through limiting resistor 21 to capacitance 22 thereby making 22 a source of direct current. In the energized position of the relay contacts 25, condenser 23 is placed in parallel with condenser 22. Consequently as the potential in condenser 22 rises at a rate influenced by the limiting resistors 21 and the line voltage, the potential rises in parallel condenser 23. Coincidentally the current through the field of relay 25 will also rise in a measure influenced by its own resistance and that of series resistor 24. When the voltage in condenser 23 has risen sufficiently to cause the relay armature to "drop in." relay switch 25 will disconnect condenser 23 from its current supply and connect it to the series shorting resistors 18 and 17. Consequently, the length of time necessary for the relay current derivative from condenser 23 to fall to the "drop out" value will be influenced by the setting of control 17 located in the manual control box.

However, as before outlined, the mechanical bias on the relay 25 is controlled by the ambient 4 temperature of bimetallic strip 29, and, consequently, the period of pulsation of the relay 25 and hence the integrated power output of heater 19 is dependent on the room temperature. Conversely, the pulse length is controllable manually by resistor 17 and so can also modulate the effective wattage of the air heater 19. Due to the appreciably different values of relay current for "drop in" and "drop out" for a given mechanical bias it has been found that the system may be easily made to operate over a 20 to 1 range of integrated power dissipation. By proper choice of components and adjustment of resistor 24 the system is caused to deliver no current to the heater 19 above any chosen "cross over" temperature. Consequently, with dropping temperature, the mechanical bias supplied by strip 29 diminishes until the relay can begin pulsing, thereby delivering increasing power to

pulsing, thereby delivering increasing power to the heater as the rate of pulsing increases. What I desire to protect by United States Letters Patent is encompassed in the following claims:

1. In a bed covering, the combination comprising an air-impervious flexible upper cover 70 member, a flexible perforated lower distribution member secured at its periphery to said upper cover member, means for forming a plurality of self-sustaining air distribution duets between said upper cover member and said lower per-

forated member, said ducts being in communication with the perforations in said lower member, a source of air pressure, and diet means communicating between said source of air pressure and said self-sustaining ducts whereby to diffuse air downwardly through the perforation, in said lower distribution member.

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2. In a bed covering, the combination comprising an air-impervious flexible upper cover member, a flexible lower distribution hierance secured to said upper cover incember, means to space intermittently said upper cover member from said lower distribution member between the points of said securance whereby to form a manifold of self-sustaining air distribution duets therebetween, said spacing means forming an array of protuberant support areas in said lower distribution member, a plurality of perforations in said lower distribution member communicating with said self-sustaining duets, a source of air pressure, and flexible duet means communicating between said source of air pressure and source of air pressure and said self-sustaining duets whereby to diffuse air downwardly from said bed covering through said perforations.

3. In a bed covering, the combination comprising an air-impervious flexible upper cover member, a flexible perforated lower distribution member, a plurality of self-sustaining air distribution duets interposed between said impervious upper member and said perforated lower member and communicating with the perforations in said lower member, a plurality of protuberant support areas formed in said lower member, a source of air pressure, and flexible duct means communicating between said source of air pressure and said self-sustaining distribution ducts whereby to diffuse air downwardly from said bed covering through said perforations.

4. In a bed covering according to claim 9, means for heating the air passing through said flexible duct means.

5. In a bed covering according to claim 9, airdrying means for drying the air passing through said flexible duct means.

6. In a device for diffusing air from a bed covering, the combination comprising a flexible self-sustaining air distribution manifold integral with said bed covering, means to diffuse air delivered by said manifold downwardly from said bed covering, an air pump, an exothermic agent for absorbing moisture from said air, heat-exchanger means for lowering the temperature of the air heated by said exothermic agent, a first duct means for conveying a portion of the air displaced by said pump first into contact with said exothermic drying agent and then into said distribution manifold for diffusion through the bed covering, and a second duct means for conveying a remaining portion of the air displaced by said pump into contact with said heat-exchanger means.

NATHANIEL B. WALES, JR.

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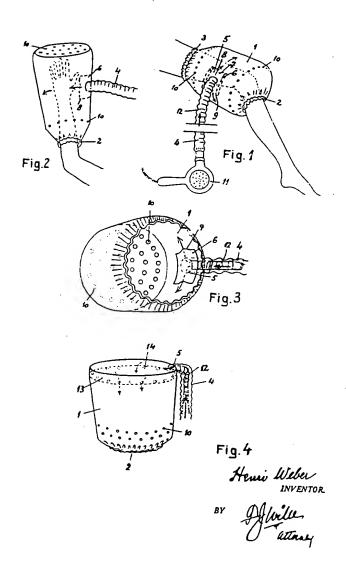
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HOMAN BODY HEAT TREATING APPARATUS

Filed Sept. 15, 1952



Patented Apr. 26, 1955

## 2,706,988

HUMAN BODY HEAT TREATING APPARATUS

Henri Weber, Zurich, Switzerland, assignor to Jarolux A. G., Zurich, Switzerland

Application September 15, 1952, Serial No. 309,660 Claims priority, application Switzerland November 19, 1951

4 Claims. (CL 128-402)

The instant invention relates to apparatus for heat treating portions of the human body of the type adapted to be connected to a source of heated air.

An object of the invention is to provide heat treating apparatus into which portions of the human body may readily be inserted and enclosed for curative heat treatment or for drying the enclosed limb, organ or hair, for example.

example.

A further object of the invention is to provide heat treating apparatus which may readily be sealed at one or two end regions thereof adjacent to the body portions being treated with heated air, and into which heated air is then admitted and given such direction within the apparatus that the heated air circulates about the body portion being treated rather than striking it directly.

Still a further object of the invention is to provide a heat treating apparatus having means to deflect the incoming heated air in such manner that the air is circulated along the interior surface region of the apparatus

lated along the interior surface region of the apparatus

wall.

I accomplish the foregoing and other objects, by providing a pliable casing open at one end, or at two opposite ends thereof, each open end having elastic means to seal off such end to the body portion adjacent the body portion being treated, with a radially extending inlet pipe substantially away from the open end, respectively ends, and beyond and adjacent to the inlet pipe internally the apparatus disposing a deflecting member adapted to intercept the radially incoming heated air and imparting thereto a substantially tangential flow about the inner surface of the apparatus. In an alternative form, the deflecting means comprises a transverse wall near one end of the apparatus between which and the closed end of the apparatus the heated air is admitted, and a plur-lity of ports disposed adjacent the periphery of the transversal wall directs the heated air longitudinally along the region adjacent the inner surface of the apparatus wall. The invention will be readily understood from the following description of several illustrative embodiments thereof in conjunction with the appended drawings in which:

Figure I shows a first embodiment of my apparatus of accomplish the foregoing and other objects, by pro-

which:
Figure 1 shows a first embodiment of my apparatus of
the two open end type adapted for the treatment of an
intermediate portion of a human limb, such as a leg or

intermediate portion of a human limb, such as a leg or arm member;
Figure 2 shows a second embodiment for the treatment of an end portion of a human limb, such as a hand or foot, or for drying hair;
Figure 3 shows a modification of the shape of the second embodiment suitable particularly for drying hair and 05 shows the deflecting means thereof from internally the apparatus; and
Figure 4 shows a third embodiment thereof in which the deflecting means is a transverse dividing wall.

Like reference characters in the various figures of the drawing identify like parts of the illustrative embodiments. Referring to the first embodiment of Figure 1, the casing 1 is of a tubular form and made of a flexible, supple material substantially impervious to air. Openings 2 and 3, at the respective ends of the tubular casing 75 1, permit the passage of a limb therethrough, and are formed of a suitable clastic yielding material, preferably one that does not lose its elasticity with repeated subjection to heated air, to seal the ends of casing 1 to the limb. A flexible air pipe 4 opens into the interior of casing I substantially radially to form the port 5 over which

2

extends a deflecting member 6, also of flexible supple material impervious to air preferably, affixed to the inner surface of the casing adjacent to port 5 and having a central inwardly spaced loose portion 7 which form a tangentially extending duct, 8 and 9, with the inner surface of the casing 1, to opposite sides of the port 5 and deflects air along the inner surface region of the casing as shown by the arrows. If desired, and to produce a powerful unidirectional circumferential blast of all the heated air admitted through the air pipe 4, one of the ducts may be closed so that all the heated air admitted must past through the one open duct. At a region removed from port 5, a plurality of air outlet apertures 10 permits the air to escape after having circulated about 5 the limb portion under treatment. The sum total of the areas of the apertures 10 is such that upon admission of heated air into the casing 1 from air inlet pipe 4 connected to any convenient source of heated air, such as the hot air blower 11, the casing will be inflated and remain inflated as long as heated air is being supplied. To assure continuous flow of heated air through the flexible pipe 4, a stiffening member such as the wire spiral 12, is incorporated in the wails of the pipe to keep it open and dilated, as also to minimize breakage thereof. Obviously instead of the hot air blower 11 shown, any source of hot air currents may be used, for example the compression side of a vacuum cleaner may be connected to pipe 4 through the intermediary of a heating element. The other illustrative embodiments of Figures 2 to 4 differ from the first embodiment in that the casing 1 in Figure 2 is in the shape of a sack, while in Figure 2 is in the shape of a cup, and in all these other embodiments only one end 2 is open and elastically yielding to seal the one pril to the limb being heat treated. The crable for the treatment of promoters and the closed casing end opposite open end 2, while in Figure 2 is in the shape of a cup, and in all these other emb

casing.

2. Heat treating apparatus according to claim 1 in which the deflecting means is supported by the inner sur-

face of the casing adjacent the port and is spaced from the port at its portion immediately registering with and adjacent to the port to form with the adjacent region of the casing a nozzle directing the admitted heated air circumferentially in at least one direction along the surface of the casing.

3. Heat treating apparatus according to claim 1 in which the deflecting means comprises a pocket of flexible material impervious to air having a loose central portion between two edge regions attached to the casing 10 regions adjacent the port, the loose central portion of the pocket forming with the casing region registering therewith a pair of oppositely directed orifices directing the heated air admitted through the port circumferentially along the interior surface of the casing in two streams 15 oppositely directed.

4. Heat treating apparatus for the heat treatment of portions of the human body comprising a pliable casing impermenable to air, a resilient opening adapted to fit closely to a portion of the human body adjacent the portion to be treated in at least one end of the casing, an air inlet port at a region of the casing spaced from the resilient opening. a flexible substantially noncollapsible pipe connected to the inlet port and adapted to pass heated air from a source into the casing, a substantially quadran-

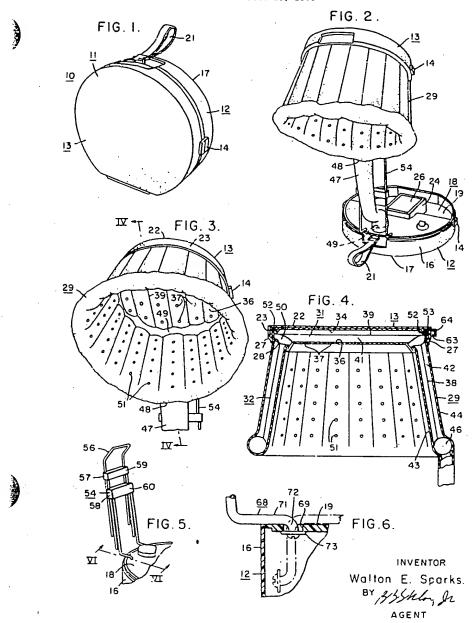
quilar strip of air imperious material attached to the interior of the easing and disposed over the infet port, the attachment being in at least two opposite strip end regions and the spacing between opposite attachments on the eylinder being at least equal to the dimension of the infet purt parallel thereto but less than the parallel dimension of the strip between steh opposite attachments so that the strip region between the attachments may be displaced away from the inner surface of the easing or passage of air through the inlet port into the easing, the displaceable partion of the strip forming with the registering easing region a pair of oppositely directed orifices directing the admitted air circumferentially along the interior surface of the easing in two oppositely directed streams, and a plurality of air outlet apertures in the easing relatively remote from the air inlet port.

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HAIR DRYER

Filed Dec. 19, 1966





3,415,140
HAIR DRYER
Walton E. Sparks, Lexington, Ohlo, assignor to Westinghouse Electric Corporation, Pittsburgh, Pa., a corporahouse Electric Curposanos, tion of Pennsylvania Filed Dec. 19, 1966, Ser. No. 602,883 10 Claims. (Cl. 34—99)

## ABSTRACT OF THE DISCLOSURE

A portable hair dryer having an inflatable hood and a support structure therefor which enables it to be used like a salon type unit by slipping the head into and out of the hood. When inflated the side walls of the hood stand away from each other to form a salon type hood 15 which when collapsed packs neatly into a compact carrying case provided therefor.

This invention relates, in general, to portable hair  $^{20}$ dryers and, more particularly, to portable salon-type hair

dryers.
Wholehearted acceptance of Lortable hair dryers dictates that they be efficient in operation, compact in size, easy to operate and afford an optimum degree of comfort 25 during use.

One model hair dryer currently available to the consumer is fashioned after the professional or commercial salon-type unit in that it has a rigid hood or bonnet which is supported on a stand to enable the user to sit thereunder. The hood is also utilized as a combination cover, for the power unit, and carrying case. Of all available portable hair dryrs, this type is probably the most efficient and least objectionable from the standpoint of discomfort during use, however, it lacks compactness and beause of its inflexibility restricts movement of the head. In other words, the head must be moved about carefully within the hood to avoid bumping of the rigidly constructed walls

The bonnet type hair dryers overcome some of the objectionable features of the portable salon-like dryer. For example, they possess the desirable features of compactness and flexible walled construction. However, they are less efficient in operation due to poor air circulation, moreover, they cause discomfort due to impressions on the forehead and pressure exerted on the ears by the elastic band or drawstring used for snugly fitting the bonnet on

From the standpoint of operation, it is desirable to have a minimum number of operations to perform in order to ready the hair dryer for use, Most portable hair dryers are cumbersome in this respect.

Accordingly, it is the general object of this exention to provide a new and improved portable hair dayer.

It is a more particular object of this invention to pro-

vide a new and improved bonnet for a portable hair dryer.

Another object of this invention is to provide a new

and improved bonnet type hair dryer which is compact in size yet highly efficient in operation.

Still another object of this invention is to provide a new and improved portable hair dryer which is eas; to operate.
Yet another object of this invention is to provide, in a

salon-type portable hair dryer, an inflatable flexible walled

Briefly, the above-cited objects are accomplished by

2

providing a hair dryer comprising a hood made from flexible vinyl plastic or other suitable material and adapted to be infiated. The hood is attached to the cover of a relatively shallow carrying case which cover serves as a storage receptacle for the hood when not in use. This is accomplished by collapsing or folding the flexible hood into the cover. The cover is provided with one part of a support structure which is adapted to receive the free end of a stand supported by the base of the carrying case. Accordingly, the base of the carrying case which houses the power means may be placed on a table such that the user can place her head into and out of the flexible bonnet which depends like an annular curtain from the carrying case cover. Since the bonnet is inflatable, it assumes a shape similar to that of a professional salon type hair dryer.

The foregoing and other objects of the present invention will become more apparent when considered in view of the following detailed description and drawings.

FIGURE 1 is a perspective view of a hair dryer, in a knocked-down condition, representing the invention: FIG. 2 is an assembled perspective view of the heir

dryer illustrated in FIG. 1; FIG. 3 is a perspective view of the bonnet portion of

the hair dryer shown in FIG. 2; FIG. 4 is a cross-sectional view taken on the line 1V-1V of FIG. 3;

FIG. 5 is an enlarged fragmentary perspective view illustrating a support structure forming a part of the preent invention; and

FIG. 6 is a cross-sectional view taken on the line VI-VI of FIG. 5.

Referring now to the drawings, especially FIG. 1, reference character 10 indicates generally a portable hair dryer comprising a carrying case 11 including a base 12 and a cover 13. The cover and base are provided component parts of a pair of latch or lock mechanisms 14 (only one of which is shown) for securing the cover 13 to the base 12 such that the cover can be completely detached therafrom as shown in FIG. 2.

The base 12 comprises a vertical annular wall 16 formed integrally with a generally circular bottom wall 17. A generally horizontal partition 18 serves as a closure for the base 22 in which power apparatus, not shown, is contained. The partition 18 is recessed or dished as at 19 to provide a storage area for a power cord, not shown. The partition 18 is also provided with an air intake 24 which carries an air filter 26. A strap 21 attached to the wall 16 of the base 12 provides means for readily carrying the dryer 10.

The cover 13 comprises a top wall 22 (see FIG. 4) formed integrally with a vertical annular wall 23 having a peripheral flange 27 with a reversed lip construction in-55 cluding an inwardly protruding portion 28

The hair dryer 10 includes an integral hood structure 29 made from any suitable material, for example, flexible viny! plastic. The hood 29 comprises a top wall structure 31 having a generally circular configuration and an-60 annular, depending or side wall structure 32. The top wall or crown structure 31 consists of an imperforate top wall 34 and a bottom wall 36 provided with a plurality of apertures 37. The walls 34 and 36 are joined, as by heat welding, along lines indicated at 39 (see FIG. 4) to thereby form a plurality of generally horizontal air distributing channels 41 to which air is conveyed (in a



manner to be more fully described hereinafter) from substantially vertical air channels 42 formed in the annular depending wall structure 32 by heat welding along the lines indicated at 38.

The wall structure 32 consists of a generally cylindrical inner wall 43 and a generally cylindrical outer wall 44 which are joined together at the bottom edges, also by heat welding. The heat welds at 38 terminate at approximately 2½" from the lower edge of the wall structure 32 thereby providing an annular oir duct 46 communicating with the vertical channels 42 to provide communication between a flexible coupling conduit 47 and the latter. One end of the conduit 47 is heat welded to the wall structure 32 as indicated at 48 (see FIGS, 2 and 4) while the other end is coupled to an air outlet 49 (shown in dotted lines in FIG. 2) provided in the partition 18 and which com-

municates with the power means, not shown.

The periphery of the imperforate top wall 34 is joined periphery of the outer wall 44 and the bottom wall 36 is joined to the inner wall 43 to form the integral 20 bonnet structure 29 (see FIG. 4). The heat welds along the lines 39 terminate at approximately one inch from the top of the wall structure 32 and the welds along the lines 38 terminate at points remote from the peripheral edge of the top wall structure 31 thereby forming a second annular air channel 49 at the jointure of the walls 34 and 36 with the walls 44 and 43, respectively. It is this channel 49 which provides the communication between the vertical channels 42 and the horizontal air channels 41. Air flow ing in the channels 41 is distributed over the top head of 30 the user through the exhaust apertures 37. Similarly air flowing through the vertical channels 42 is distributed over the sides, front and back of the head through exhaust apertures 51 and in the inner wall 43.

A flexible cylindrical band 52 (see FIG. 4) attached in 35 any suitable manner, as by gluing to outer wall 44 at the top thereof, is insertable in a continuous groove 53 formed between the top wall 22 and the inwardly projecting portion of the peripheral flange 27, the band 52 being capti-

vated therein by the inwardly projecting portion 28.
In this manner the bonnet 29 is adapted to be supported for use by the cover 13 which is, in turn, carried by an extensible or telescopic stand or support structure 54 (best shown in FIG. 5).

The support structure 54 comprises U-shaped rods 56, 57 and 58 coupled together by connecting members 59 and 60. Each of the U-shaped members 57 and 58 has a straight bight portion which is insertable in slots in the undersides of connecting members 59 and 60. The bight portion of the U-shaped rod 56 is insertable in a slot 63 (see FIG. 4) formed by a portion of the annular wall 16 and a complementary part 64 suitably secured thereto. The bight portion of the rod 56 is slightly offset from the legs thereof in order to provide the proper angle of inclination of the cover 13 and, consequently, the bonnet 29 when 55 the cover is mounted thereon.

The legs of the U-shaped rods 56 and 57 are slidable within elongated bores 66 and 67 provided in the connecting members 59 and 60 to permit variation of the height of the bonnet. The legs of the U-shaped rod 58 are 60 offset as indicated at 68 (see FIG. 6) and are inserted through apertures 69 in the partition 18 such that the legs of the offset segments 68 move freely therethrough for permitting the supporting structure 54 to be folded flat for storage on top of the partition 18. Each of the offset segments 68 includes two legs 71 and 72, the latter of which is provided with an outwardly projecting flange 73, in the form of a washer captivated by a screw 74, which cooperates with the underside of the partition 18 to retain the support structure in the operating position.

Since numerous changes may be made in the above described apparatus and different embodiments of the invention may be made without departing from the spirit thereof, it is intended that all matter contained in the 75

foregoing description or shown in the accompanying Jrawings, shall be interpreted as illustrative and not in a limiting sense. What is claimed is:

1. In a postable hair dryer, hood structure comprising: a side wall structure of generally circular cross section in-cluding a flexible outer wall and a flexible inner wall, a crown structure including a flexible top wall and a flexible bottom wall each having a generally circular shape, said top wall structure being joined to said side wall structure at one end of the latter, said top and bottom wails being joined at spaced intervals to provide air circulating channels therebetween, said inner and outer walls being joined at spaced intervals to provide air circulating channels therebetween, at least some of said channels in said side wall structure being in communication with some of said channels in said crown structure, means for introducing air into said channels in said side wail structure at the end thereof opposite said crown structure, said bottom and inner walls having apertures communicating with said channels for permitting air in said channels to exhaust

2. Structure as specified in claim 1, wherein the top wall is joined to said outer wall and said bottom wall is joined to said inner wall to provide an annular air circu-

lating channel thereat.

3. Structure as specified in claim 1, wherein the air channels in said side wall structure are disposed along the longitudinal axis thereof and the jointure between said inner and outer walls terminate intermediate the ends of said side wall structure and the periphery of said crown structure to thereby provide an annular air circulating channel at the end thereof opposite said crown structure.

4. Hair drying apparatus comprising: a carrying case including a base having an air inlet and outlet and a detachable cover, an inflatable hood, said hood comprising a crown structure and a side wall structure of generally circular cross section joined thereto, each of said structures being provided with air circulating channels and exhaust apertures, said cover having a top wall and an annular wall integral therewith, means for securing said bood adjacent said crown structure to said cover, means carried by said base for supporting said cover above said base whereby said side wall structure depends the afrom for insertion and removal of the head to be dried, said hood being collapsible into said cover for storage thereof in said case and means interconnecting said air outlet means with said hood for conveying air therebetween.

5. Structure as specified in claim 4, wherein said air conveying comprising a flexible conduit and which includes means for permanently attaching said conduit to said outlet and said hood.

6. Structure as specified in claim 4, wherein said support means comprises relatively movable sections whereby said cover may be supported at various levels above said

7. Structure as specified in claim 4, wherein said support structure is adapted for movement from an inoperative position wherein it lies substantially parallel to said base to an operative position wherein it is substantially perpendicular to said base.

8. Structure as specified in claim 4, wherein said crown structure comprises a top wall and a flexible bottom wall, said top and bottom walls being joined along lines at spaced intervals to provide air circulating channels therebetween, said side wall structure including an inner wall and an outer wall joined along lines at intervals along the circumference thereof to provide air circulating channels therebetween, at least some of said side wall channels being in communication with said crown channels.

. Structure as specified in claim 8, wherein said top wall is joined by heat welding to said outer wall and said bottom wall is joined to said inner wall to provide an annular air circulating channel thereat.

10. Structure as specified in claim 9, wherein the side

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wall jointures extend along the longitudinal axis of and	3,168,382	2/1965	Chambers et al 3499
are disposed intermediate the ends of said side wall struc-	3,267,587	8/1966	Niemiec et al 34-99
ture whereby there is provided an annular air channel adjacent both ends of said side wall structure.	3,330,048	7/1967	Rogers et al 3499
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CHARLES J. MYHRE, Primary Examiner. A. D. HERRMANN, Assistant Examiner.

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[32]	Priority	July 25, 1968	
[33]		Great Britain	
1311		35673/68	
[54]	<b>HUMAN B</b>	CE FOR THE HEAT TREATM BEING I Drawing Figs.	AENT OF A
(52)	U.S. Ct		128/379
			/164, 128/400
1511	Int. Cl		
		ercb	
(50)		2.1 A, 2.1, 2, DIG. 1; 128/379,	
	•	4/164, 165, 160; 16	
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ABSTRACT: An appliance suitable for use in the heat treatment of a human being comprising a loose-fitting, body enveloping, baglike garment of a flexible, nonporous material closed at the bottom end, the other end, which is open, terminating in a neckband, which is preferably adjustable. A conduit is connected to the closed end of the garment for the supply of hot dry air to the interior of the suit. Apertures are punched in the garment in positions remote from the conduit connection for the escape of hot air. The garment may optionally have arms with adjustable cuffs and in which case the apertures are located adjacent the cuffs.

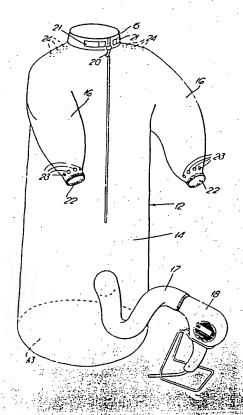
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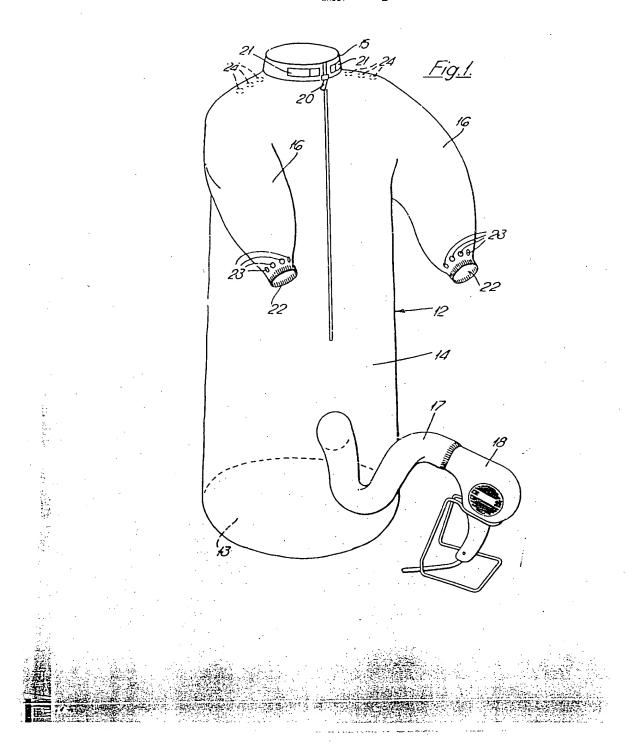
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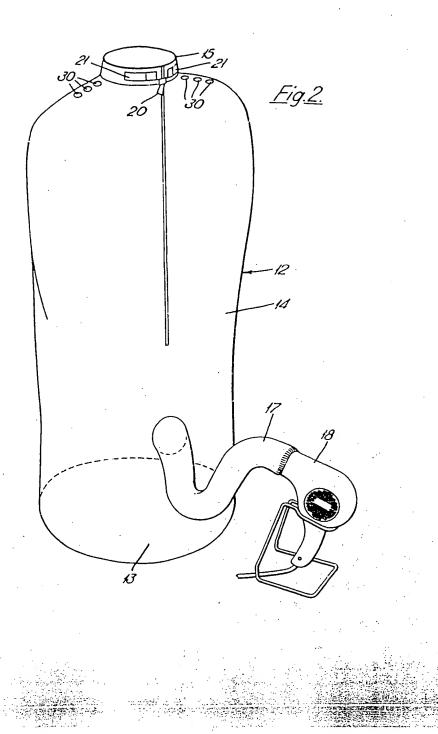
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SHEET 1 OF 2



SHEET 2 OF 2



#### APPLIANCE FOR THE HEAT TREATMENT OF A HUMAN BFING

The present invention relates to an appliance to be worn by a human being and which is suitable for use in heat therapy and for simulating the physical and psychological effects of a

In a sauna bath a person wholly or partially encases their body and subjects their body to dry heat. This is contrary to a steam or Turkish bath in which the body is subjected to wet 10

Sauna haths are of such a construction as to render them relatively expensive to manufacture. It is therefore an object of the invention to provide an appliance which simulates to the user the physical and psychological effects of a sauna bath but which is inexpensive to manufacture.

According to a first aspect of the present invention there is provided an appliance suitable for use in the heat treatment of a human being, comprising a baglike garment of a size sufficient to accommodate an adult human being and which is 20 closed at one end, a neckband at the other end, a conduit for connection to a hot air blower communicating with the interior of the garment and a plurality of apertures in the garment remote from the conduit entry.

According to a second aspect of the present invention, there 22 is provided an appliance suitable for use in the heat treatment of a human being, comprising a baglike garment of a size sufficient to accommodate an adult human being and which is closed at one end, a neckband at the other end, two sleeves with adjustable cuffs, a conduit for connection to a hot air blower communicating with the interior of the garment and a plurality of apertures in the garment remote from the conduit

Preferably the neckband is adjustable to suit the neck size of 35

If desired, the conduit may be connected to the garment at a point adjacent to, but spaced from, the closed end of the gar-

The apertures may be arranged adjacent to, but spaced from, each cuff. Further apertures may be provided between the top of each sleeve and the neckband.

According to a third aspect of the invention there is provided the combination of a hot air blower and an appliance suitable for use in the beat treatment of a human being comprising a baglike garment of a size sufficient to accommodate an adult human being and which is closed at one end, an adinstable neckband at the other end, two sleeves with adjustable cuffs, a conduit for connection to the hot air blower and communicating with the interior of the garment and a plurality 50 of apertures in the garment remote from the conduit entry.

For convenience in the following description the appliance will be referred to as a sauna suit.

Embodiments of the invention will now be described, by way of example, with reference to the accompanying 55 drawings, in which:

FIG. 1 is a perspective view of a preferred embodiment of a sauna suit with sleeves; and

FIG. 2 is a perspective view of a sleeveless sauna suit.

In the drawings similar reference numerals have been used 60 to identify similar parts.

Referring to FIG. 1, the sauna suit 12 comprises a baglike garment made from lightweight flexible material such as polyvinylchloride (P.V.C.) or woven nylon fabric backed with rubber or plastics material. The garment comprises a substan- 65 tially circular base 13 of between 18 and 24 inches in diameter, a barrel-shaped body portion 14, an adjustable nackband 15, sleeve 16 and a flexible conduit 17 communicating with the interior of the body portion 14. The sauna suit 12 is of such a size as to be a very generous fit on the user thereby facilitating the circulation of hot dry air introduced into the suit from a hot air blower 18, e.g. a domestic hair drier, connected to the conduit 17.

A sliding clasp fastener or closure member 20 is fitted into the front of the suit 12 to facilitate the entry by a user into the 75 

suit. The closure member 20 may extend in other directions besides down the front of the suit, for example, along the shoulders or towards the armpit. The size of the neckband 15 is adjustable by means of nylon limpet strips 21 each comprising two parts, one in the form of barbs on a material backing and the second in the form of a strap having a looped or woolly surface which when engaged by the barbs is secured thereto. Alternatively, in a nonillustrated embodiment, the neckband 15 can be elasticated or adjusted in size by means of drawstrings.

The sleeves 16 terminate in cuffs 22 which are elasticated to grip the wrists of the user. A series of circular apertures 23, e.g. eight apertures of about a quarter of an inch in diameter are punched out of each sleeve 16 about five inches from the respective cuff 22. The apertures 23 are provided to facilitate the exit of hot air from the suit after it has circulated through the body portion 14. If desired, further apertures 24, shown in broken lines, may be provided in each shoulder of the suit.

The flexible conduit 17 is preferably made of the same material as the rest of the suit. The free end of the conduit 17 is elasticated to grip the outlet of the hot air blower 18. Typical dimensions of the conduit 17 are that it is 18 inches long and 3 inches in diameter. The connection of the conduit 17 to the body portion 14 is at approximately seven inches from the adjacent edge of the circular base 13.

The preferred mode of using the sauna suit is with the user in a relaxed sitting position in an environment at a temperature of between 65° F. and 70° F.

The user undresses and then enters the suit by unfastening the closure member 20 and climbing in one leg at a time. The arms are passed through the sleeves 16 so that the hands are exposed thereby enabling the user to fasten the closure member 20.

The nylon limpet strips 21 at each side of the neckband 15 are adjusted until the neckband is a tight but comfortable fit on the user's neck

The conduit 17 is connected to the outlet of the blower 18 which has been placed in a convenient position. Naturally, precautions should be taken to ensure that the conduit is not bent or twisted thereby ensuring that the flow of air is not impeded. The blower 18 is then switched on and the suit is inflated by hot air from the blower. It is desirable from the point of view of user comfort that the temperature of the air at the outlet of the blower should not exceed 200° F.

After a period of at least 30 minutes, and not exceeding 60 minutes, the blower is switched off and the user removes the sauna suit.

Referring to FIG. 2, the illustrated sauna suit 12 differs from that of FIG. 1 by being sleeveless and by having apertures 30 along each shoulder only. With this embodiment it is necessary for a user to be assisted into and out of the suit 12.

In each of the illustrated embodiments by having the apertures remote from the conduit connection, the circulation of hot air over the major part of the user's body is ensured. It is within the scope of the present invention to connect the conduit to another part of the garment and to arrange the apertures so that the hot air follows a path over the major part of the user's body.

It is to be understood that the invention herein is described in specific respects for the purposes of this description. It is also understood that such respects are merely illustrative of the application of the principles of the invention. Other arrangements may be devised by those skilled in the art without departing from the spirit and scope of the invention.

1. An appliance suitable for use in the heat treatment of a human being, comprising

a. a garment having an elongate tubular body member of single layer, nonporous, flexible material generally cylindrical in shape with a substantially flat bottom thereby providing an unobstructed interior throughout the length of the garment, the lower end of the body member being closed, means defining a neck opening in said garment, a

neckband in said neck opening, means enabling the size of said neckband to be adjustable, an elongate entrance alit extending from said neck opening, fastening means for releasably closing said entrance slit, arm receiving extending outwardly from said body member, cuffs on said 5 sleeves, means enabling the size of the cuffs to be adjustable, means defining unobstructed apertures in said sleeves adjacent to, but spaced from, the cuff on each sleeve, a flexible conduit attached to and communicating with the interior of said body member through an unobstructed 10

opening, said opening positioned adjacent to, but spaced from, said lower end, and

b. a portable hot air blower connected to said conduit to direct hot air into said body member and out through said apertures.

 An appliance according to claim 1, further comprising means defining apertures adjacent to, but spaced from, said neckband.

Feb. 6, 1973 [45]

	THEOTE	TOTAL DADY BUNTING		
[54]	HYPOTHERMIA BABY BUNTING			
[75]	Inventor:	John C. Hardy, Weatogue, Conn.		
[73]	Assignee:	Angelica Corporation, St. Louis.		
[22]	Filed:	Feb. 11, 1971		
[21]	Appl. No.	: 114,466		
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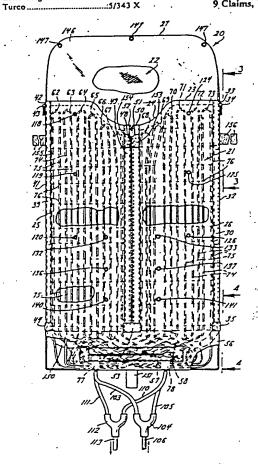
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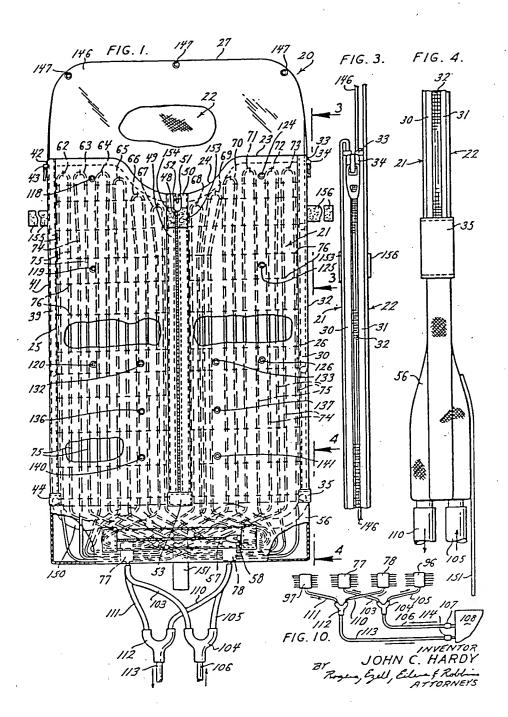
## ABSTRACT

An infant's hypothermia bunting having front and rear panels of two-way stretch fabric. Longitudinally extending tubes connected to the front and rear panels for conveying temperature-controlled fluid. Snap fasteners for adjusting the lateral size of the bunting and snap fasteners for adjusting the longitudinal size of the bunting to conform to different infant body. of the bunting to conform to different infant body sizes. Zippers at the center and sides of the bunting to provide body access for hospital purposes. A plastic liner releasably fastened to the rear panel for distributing the loads of tube projections. A pocket at the bottom of the bunting for containing manifolds collecting inlet ends of the tubes and outlet ends of the tubes for common connections to the inlet and outlet fittings of a hypothermia machine.

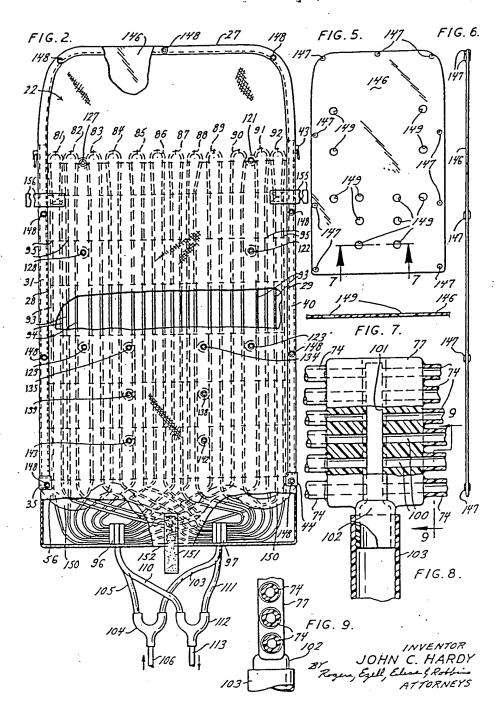
9 Claims, 10 Drawing Figures



128/400 X



SHEET 2 OF 2



HYPOTHERMIA BABY BUNTING
This application is a continuation-in-part of application Ser. No. 114,607 filed on Feb. 11, 1971.

## BRIEF DESCRIPTION OF THE INVENTION:

This infant's hypothermia bunting controls an infant's body temperature for hospital purposes, such as surgical operations. Loss of body heat during preparation for surgery produces adverse physiological effects which can be critical, particularly for premature infants. It is important that the body temperature of the infant be controlled efficiently and uniformly over the entire body of the infant.

Most prior art systems circulate water through plastic tube blankets or pads which are stiff and do not conform to the body, resulting in inefficient heat transfer and local hot and cold spots. These prior art systems that incorporate plastic blankets or pads are heavy and therefore preclude covering the front of the finfant's body leaving large exposed body surface areas and consequent loss of body heat. The prior art systems include fluid transport tubes sandwiched between two impermeable plastic plys, limiting sterilization and laundering. They are very uncomfortable, particularly to those areas of the infant's body that rest on body supporting surfaces. The impermeable construction limits breathing and evaporation of body moisture, adding to discomfort.

This infant's hypothermia garment comprises front 30 and rear panels of stretch fabric. The panels are rectangular in shape and are joined at their sides and bottom edges. The upper edges are separable to provide an opening for receiving an infant's body into the envelope between the front and rear panels.

The bunting encloses the body of the infant from the neck down. Several fluid conveying tubes are attached to the inner surfaces of the panels by stitching or by an attachment method set forth in a co-pending applica-. tion of the present inventor filed in close proximity to 40 the filing date of the present application and identified as Rogers, Ezell, Eilers and Robbins Docket 16,484 entitled Method of Joining Tubes to Fabrics. The tubes extend longitudinally along the panels to permit and not interfere with lateral or circumferential expansion 45 of the bunting to conform to the contour of the infant's body. Each tube consists of a supply pass and a return pass. The supply passes lead from inlet manifolds, and the return passes return to outlet manifolds. The manifolds are located in a pocket at the bottom of the 50 bunting and are connected by tubes to a hyperthermia machine that circulates temperature controlled fluid through the tubes. The supply passes and return passes are alternated to effect substantially uniform temperature distribution over the entire inner surfaces of the 55 bunting.

Two longitudinal lines of snap fasteners are spaced inwardly of the side edges of the front and rear panels for adjustment of the width of the inner envelope of the bunting. Three lateral lines of snap fasteners are spaced upwardly from the lower edges of the front and rear panels to adjust the depth of the inner envelope. These snap fasteners thus vary the effective volume of the bunting so that it can be made to conform to different sizes and shapes of infant's bodies, with the stretch fabric material of the bunting providing further conformity to the contour of the infant's body.

A plastic liner has snap fasteners around its edges for releasable fastening to the inner surface of the rear panel to distribute the load and pressure created by the fluid conveying tubes. The panel is removable for sterilization of the panel and for sterilization and laundering of the bunting.

# BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a front elevation view of the infant's hypothermia bunting with parts broken away:

FIG. 2 is a rear elevation view of the infant's hypothermia bunting with parts broken away:

FIG. 3 is an enlarged fragmentary right side elevation view taken along the line 3—3 of FIG. 1;

FIG. 4 is an enlarged fragmentary right side elevation view taken along the line 4—4 of FIG. 1;
FIG. 5 is a front elevation view of the plastic liner on

a reduced scale;

FIG. 6 is a right side elevation view of the plastic liner of FIG 5 on the scale of FIGS. 1 and 2;

FIG. 7 is an enlarged fragmentary view in section taken along the line 7—7 of FIG. 5;

FIG. 8 is a front elevation view of an enlarged scale of a manifold with parts shown in section;

FIG 9 is a fragmentary view in section taken along the line 9-9 of FIG. 8;

FIG. 10 is a schematic view of the connections of the manifold to a hyperthermia machine.

# DETAILED DESCRIPTION OF THE INVENTION

This bunting 20 has a front panel 21 that is about 18 inches wide and 24 inches long and a rear panel 22 that is the same width as the front panel and is about 30 35 inches long. The foregoing lengths are exclusive of a bag at the lower end of the bunting to be described hereinafter. The front panel 21 has an upper edge 23 with a downwardly curved center 24 positioned where the neck of an infant within the bunting would be located, and has side edges 25 and 26. The rear panel 22 has an upper edge 27 that is about 6 inches above the upper edge 23 of the front panel and has side edges 28 and 29. The side edges 26 and 28 of the front and rear panels respectively are sewed to the front and rear cloth bindings 30 and 31 of a zipper 32. The zipper 32 has a separator start element 33 at its upper end and a slider 34 that can fully open the zipper 32 with the upper ends separated down to a cloth stop element 35 at the lower end of the zipper that is sewn to the front and rear panels 21 and 22.

The other side edges 25 and 29 of the front and rear panels respectively are similarly sewn to the front and the rear cloth bindings 39 and 40 of a zipper 41. The zipper 41 has a separator start element 42 at its upper end and a slider 43 that can open the zipper 41 with the separator element 42 separated and the zipper 41 separated all the way down to a cloth stop element 44 that is sewn to the front and rear panels 21 and 22 at the lower end of the zipper 41.

A zipper 48 extends longitudinally along the center of the front panel 21. The side cloth bindings 49 and 50 of the zipper 48 are sewn to the front panel 21. The zipper 48 has a separator start element 51 at its upper end. A slider 52 can open the zipper 48 with the separator element 51 separated and the zipper 48 separated all the way down to a cloth stop element 53 sewn to the front panel 21 at the lower end of the zipper 48.

The front and rear panels 21 and 22 continue below the cloth zipper stop elements 35, 44 and 53 and are sewn together at their side and bottom edges to form a bag 56. A lateral zipper 57 having a slider 58 provides access to the interior of the bag 56.

There are 12 tubes 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72 and 73 extending longitudinally of and fastened to the inner surface of the front panel 21, six of the tubes 62 through 67 being fastened to the front panel between the zippers 41 and 48 and the other six tubes 68 through 73 being fastened to the front panel between the zippers 48 and 32. Each tube 62 through 73 has a supply pass 74 and a return pass 75. The tubes 62 through 73 may be attached to the panel 21 by stitches 76 spaced at about 3-inch intervals or they may be attached by the method set forth in a co-pending application of the present inventor filed at about the same time as the present application and identified by Rogers, Ezell, Eilers and Robbins Docket 16484, entitled Method of Joining Tubes to Fabrics. The tubes 62 through 73 are arranged such that supply passes 74 alternate with return passes 75 and are substantially evenly spaced to distribute temperature-controlled fluid uniformly over the entire surface area of the bunt- 25

The lower ends of the supply passes 74 of the tubes 62 through 73 extend downwardly into the bag 56 and are connected to a supply or inlet manifold 77. The lower ends of the return passes 75 of the tubes 62 30 through 73 extend downwardly into the bag 56 and are connected to a return or outlet manifold 78.

Twelve tubes 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, and 92 are fastened to the inner surface of the rear panel 22. Each tube 81 through 92 has a supply pass 93 35 and a return pass 94. The tubes 81 through 92 are substantially evenly spaced across the width of the panel 22 with supply and return passes 93 and 94 alternating with one another and substantially evenly spaced. The tubes are connected to the panel 22 by spaced stitches 40 95 or by the method of the aforesaid co-pending application. All the ends of the supply passes 93 extend downwardly into the bag 56 and are connected to a supply or inlet manifold 96. The lower ends of the return passes 94 extend downwardly into the bag 56 45 and are connected to a return or outlet manifold 97. The tubes 62 - 73 and 81 - 92 are small and flexible being about one-eighth inch to five-thirty seconds inch in outside diameter.

FIG. 8 illustrates a typical manifold 77, the other manifolds 78, 96, and 97 being identical thereto. The tubes 74 are connected to the manifold 77, each communicating with a passage 100. Each passage 100 communicates with a central passage 101 provided by a central tube 102 to which a tube 103 is connected. These manifolds may be made by the process set forth in the present applicant's co-pending application filed at about the same time as the present application and being identified as Rogers, Ezell, Eilers & Robbins Docket 16485 entitled Method Of Joining Tubes To A Manifold.

In the case of the supply manifold 77, the tube 103 leads from a Y fitting 104. The other supply manifold 96 similarly has a tube 105 leading from the Y fitting 104. A tube 106 leads to the Y fitting 104 from an outlet connector 107 of a hyperthermia machine 108 of a conventional kind that circulates temperature-con-

trolled fluid, such as water. The tube outlet manifolds 78 and 97 have tubes 110 and 111 respectively leading to a Y junction 112. A tube 113 from the Y juncture 112 leads to an inlet connector 114 to the hyperthermia machine 108.

This infant's hypothermia bunting has sizing adjustments that permit it to accommodate infants up to the age of about six months. Three snap fasteners 118, 119 and 120 are arranged in a longitudinal row and are joined to the front panel 21. The snap fasteners 118, 119, and 120 are spaced inwardly about three inches from the left side edge of the front panel 21. Three snap fasteners 121, 122, and 123 that are complementary to the snap fasteners 118, 119, and 120 are joined to the rear panel 22. The snap fasteners 121, 122, and 123 are in a longitudinal row and are located directly opposite the snap fasteners 118, 119, and 120.

A similar row of three snap fasteners 124, 125, and 126 is spaced about three inches longitudinally inwardly from the right front edge of the bunting. The snap fasteners 124, 125, and 126 are joined to the front panel and are located directly opposite three snap fasteners 127, 128 and 129 that are joined to the rear panel 22.

Two snap fasteners 132 and 133 are laterally aligned with the snap fasteners 120 and 126 and are joined to the front panel 21. The line of snap fasteners 120, 132 133 and 126 is spaced above the lower edge of the bunting 20 by about eleven inches, the lower edge being defined as an imaginary line through the fabric zipper stops 44, 53, and 35 above the bag 56. Two snap fasteners 134 and 135 are joined to the rear panel 22 in positions directly opposite the snap fasteners 132 and 133 and in line with the snap fasteners 129 and 123. The snap fasteners 134 and 135 are complementary to the snap fasteners 132 and 133.

Two laterally aligned snap fasteners 136 and 137 are joined to the front panel 21 approximately 4 inches below the snap fasteners 132 and 133. Two snap fasteners 138 and 139 that are joined to the rear panel 22 are opposite to and complementary to the snap fasteners 136 and 137. Another two snap fasteners 140 and 141 are laterally aligned and spaced approximately four inches below the snap fasteners 136 and 137 and are joined to the front panel 21. Two complementary snap fasteners 142 and 143 are joined to the rear panel 22 and are positioned opposite the snap fasteners 140 and 141.

The lines of longitudinal snap fasteners 118 and 119 and 120 and 121, 122, and 123 and the lines of longitudinal snap fasteners 124, 125, and 126 and 127, 128 and 129 can be snapped together to reduce the circumferential size of the bunting 20, or just one longitudinal line of snap fasteners may be snapped together, thus providing circumferential adjustment to an infant's body size. The lateral line of snap fasteners 120, 132, 133, and 126 may be snapped to the snap fasteners 123, 134, 135, and 129 for depth adjustment. Alternatively, the snap fasteners 136, 137, 138, and 139 may be snapped together or the snap fasteners 140, 141, 142, and 143 may be snapped together to provide variations in depth adjustment for infant body lengths. Following such coarse adjustment of the inner envelope, the stretch fabric of the panels 21 and 22 causes the bunting to conform to the body of the infant. A plastic liner 146 is shaped to overlie the inner surface of the rear panel 22, forward of and overlying the tubes 81 - 92. The plastic liner 146 has spaced snap fasteners 147 adjacent to its upper and side edges. The rear panel 22 has forwardly projecting spaced snap fasteners 148 adjacent its upper and side edges complementary to the snap fasteners 147. The liner 146 also has holes 149 through it located to permit the various size adjustment snap fasteners 118 through 129 and 132 through 143 to be snapped together. All adjustment snap fasteners are reinforced by the plastic discs to prevent the snaps from pulling from its mounting substrate.

In use, an infant's body from the neck down is located within the envelope between the front and rear panels 21 and 22. Depending upon the size of the infant's body, different ones of the size adjustment snap fasteners are snapped together or, for a relatively large infant, all the size adjustment snap fasteners are left unsnapped. The front zipper 48 and two side zippers 32 20 and 41 can be unzipped for easier entry of the infant into the bunting. Also, these zippers provide flexibility of access to the infant's body for hospital and surgical purposes.

With the infant in the bunting, the stretch fabric 25 holds the bunting in conformity with the infant's body. Temperature controlled fluid is circulated through the one-eighth to five thirty-seconds inch outside diameter tubes 62 through 73 and 81 through 92 so that the ineven in relatively cool operating atmospheres. The liner 146 eliminates pressure points from the tubes 81 through 92. For laundering and sterilization of the bunting, the lining 146 can be removed. This permits sterilization of the liner 146 also.

Thus, this infant's hypothermia bunting provides efficient heat transfer to the infant's body. The two directional stretch fabric of the front and rear panels 21 and 22 conforms the tubes to the infant'2 body. The alternating of supply and return passes of the tubes provides substantially uniform temperature distribution over the entire surfaces of the front and rear panels 21 and 22. At the same time, comfort is provided by the porosity of the fabric of the front and rear panels 21 45 and 22.

The bunting is light in weight and the fabric is soft and flexible so that is not uncomfortable when resting. on the infant's body. The rear liner 146 distributes the profiles of the tubes 81 through 92. This liner is made of high thermal conductivity plastic for increased heat transfer.

With the adjustment snap fasteners, the bunting can months. The locations of the size adjustment snap fasteners tapers the inside envelope to conform to the natural taper of the torso and legs of the infant.

Zipper bindings 30, 31, 39 and 40 and Zipper stop elements 35 and 44 made from electrostatically con- 60 ductive cloth and communicate electrostatically with another conductive cloth strip 150 located inside the pouch 56. The conductive cloth strip 150 is attached directly to zipper stop elements 35 and 44, and also to a conductive velcro pile strip 151 (pile facing down) located along the pouch centerline to electrostatically ground the bunting to the operating table. Strip 151 is

secured to the outer rear surface of pouch 56 along the centerline of the bunting with stitching 152.

Velero pile tabs 155 and 156 (approximately 2 inches by 10 inches) are attached to the outside rear panel 22 surface by stitches (approximately 2 inches of stitching and 8 inches free length). Velcro hook tabs 153 and 154 are located along the zipper bindings 50 and 49 respectively in the same horizontal line as tabs 155 and 156. The tabs are so arranged that when the right-hand side of front panel 21, as viewed in FIG. 1, is opened and folded or rolled back to permit surgery on the left side of an infant, the tabs 156 and 154 are pressed together to hold that right-hand side firmly against the infant's torso. Conversely, when the lefthand side of front panel 21 is opened and folded or rolled back to permit surgery on the right side of an infant, the tabs 155 and 153 are pressed together to hold that left-hand side firmly against the infant's torso. When not required, the tabs 155 and 156 are folded under the rear panel 22 of the bunting.

Various changes and molifications may be made within this invention as will be readily apparent to those skilled in the art. Such changes and modifications are within the scope and teaching of this invention as defined by the claims appended hereto.

What Is Claimed Is: 1. An infant bunting for enclosing the body of an infant and for controlling the body temperature of said fant's body heat can be maintained at a desired level 30 infant comprising a flexible enclosure sized to receive said body of said infant, said enclosure having a front portion disposable in register with the front of said body of said infant and having a rear portion disposable in register with the rear of said body of said infant, tubing which is connected to the surface of said front portion of said enclosure in a pattern distributing said tubing over substantially the entire surface of said front portion of said enclosure that contacts said front of said infant's body and which confines and guides heatexchanging fluid for movement in heat-exchanging relation with respect to said front of said infant's body, further tubing connected to the surface of said rear portion of said enclosure in a pattern distributing said further tubing over substantially the entire surface of said rear portion of said enclosure that contacts said rear of said infant's body and which confines and guides heat-exchanging fluid for movement in heatexchanging relation with respect to said rear of said inloads that otherwise would be caused by the protruding 50 fant's body, means to control the temperature of said heat-exchanging fluid moving through the first said tubing and also through said further tubing, releasable fastener means on said front portion of said enclosure which are spaced inwardly from edges of said front porbe sized to fit all infants up to the age of about 6 55 tion of said enclosure, and complementary releasable fastener means on said rear portion of said enclosure which are spaced inwardly from edges of said rear portion of said enclosure, the first said releasable fastener means being in register with and being selectively securable to and releasable from said complementary releasable fastener means, the first said releasable fastener means and said complementary releasable fastener means being releasable from each other to permit a large amount of the area of said front portion of said enclosure to be moved far enough away from a corresponding amount of the area of said rear portion of said enclosure to enable said bunting to accommodate but confine the body of a large infant, the first said releasable fastener means and said complementary releasable fastener means being securable together to join said front portion of said enclosure to said rear portion of said enclosure at points which are spaced in- 5 wardly of said edges of said front portion and of said rear portion of said enclosure, and thereby reduce the amount of area of said front portion of said enclosure which can be moved far enough away from a corresponding amount of the area of said rear portion of said enclosure to accommodate but confine the body of a smaller infant, whereby selective securing or releasing of the first said releasable fastener means and of said complementary releasable fastener means readily and directly varies the effective size of said bunting for conformance of said bunting to the bodies of infants of varying sizes.

2. The infant bunting of claim 1 wherein said front portion of said enclosure is a front panel, wherein said 20 other through said openings. rear portion of said enclosure is a rear panel, wherein the first said releasable fastener means are individual and discrete fasteners longitudinally aligned and spaced inwardly from the side edges of said front panel laterally aligned and spaced upwardly from the lower edge of said front panel, wherein said complementary releasable fastener means are individual and discrete fasteners longitudinally aligned and spaced inwardly from the side edges of said rear panel and are further 30 individual and discrete fasteners laterally aligned and spaced upwardly from the lower edge of said rear panel, whereby the first said releasable fastener means and said complementary releasable fastener means coact to permit said effective size of said bunting to be adjusted longitudinally as well as laterally.

3. The infant bunting of claim 1 wherein said front portion of said enclosure is made of stretch fabric that is stretchable in at least the lateral direction, wherein said rear portion of said enclosure is made of stretch fabric that is stretchable in at least the lateral direction, wherein the first said releasable fastener means and said complementary releasable fastener means coact to provide a coarse size adjustment in the lateral direction, and wherein the stretchable nature of said stretch fabric of said front portion and of said rear portion of said enclosure enable said front portion and said rear portion of said enclosure to provide a fine size adjustment in the lateral direction.

4. The infant bunting of claim I wherein the first said tubing is fluid conveying tubing, wherein said further tubing is fluid conveying tubing, wherein the first said tubing comprises a plurality of individual tubes each tube spans of the first said tubing are located with supply spans alternating with return spans for uniform temperature distribution over the surface of said front portion of said enclosure, wherein said further tubing comprises a further plurality of individual tubes each having a supply span and a return span, wherein the tube spans of said further tubing are located with supply spans alternating with return spans for uniform temperature distribution over the surface of said rear portion of said enclosure, wherein supply manifold means supply fluid to said supply spans of the first said and said further tubing, and wherein return manifold

means receive fluid from said return spans of the first said and said further tubing.

5. The infant bunting of claim 1 wherein said front portion of said enclosure is a front panel, wherein said rear portion of said enclosure is a rear panel, wherein the first said releasable fastener means are individual and discrete fasteners, wherein said complementary releasable fastener means are further individual and discrete fasteners, wherein a pressure-distribution liner is releasably fastened to said rear panel, wherein said pressure-distribution liner overlies said further tubing and can distribute evenly to said body of said infant the forces which said further tubing otherwise would distribute unevenly to said body of said infant, and wherein said pressure-distribution liner has openings therein in register with the first said and said further releasable fastener means to enable the first said and said further releasable fastener means to engage each

6. An infant bunting for controlling body temperature comprising front and rear panels joined at their side and bottom edges to form a pocket open at its upper end to receive the body of an infant, a plurality and are further individual and discrete fasteners 25 of small-diameter tubes fastened in a substantially uniformly spaced array to a surface of said front panel, a second plurality of small-diameter tubes fastened in a substantially uniformly spaced array to a surface of said rear panel, each tube of the first said plurality of smalldiameter tubes having a supply span for receiving temperature-controlled fluid and a return span for returning said temperature-controlled fluid after said temperature-controlled fluid has been in heat-exchanging relation with said body of said infant, each tube of said second plurality of small-diameter tubes having a supply span for receiving temperature-controlled fluid and a return span for returning said temperature-controlled fluid after said temperature-controlled fluid has been in heat-exchanging relation with said body of said infant, distributor means to receive said temperaturecontrolled fluid from a source of temperature-controlled fluid and to supply said temperature-controlled fluid to said supply spans of said tubes of the first said plurality of small-diameter tubes and to supply said temperature-controlled fluid to said supply spans of said tubes of said second plurality of small-diameter tubes and thereby enable the first said plurality and said second plurality of small-diameter tubes to circulate 50 temperature-controlled fluid in heat-exchanging relation with said body of said infant, further distributor means connected to said return spans of said tubes of the first said plurality of small-diameter tubes and to said return spans of said tubes of said second plurality having a supply span and a return span, wherein the 55 of small-diameter tubes to receive said temperaturecontrolled fluid from said tubes of the first said plurality and said second plurality of small-diameter tubes after said temperature controlled fluid has been in heat-exchanging relation with said body of said infant and to return said temperature-controlled fluid to said source of temperature-controlled fluid, releasable fastener means on said front panel that are distributed longitudinally and laterally of said front panel, complementary releasable fastener means on said rear panel that are distributed longitudinally and laterally on said rear panel, the first said releasable fastener means and said complementary releasable fastener means being

releasable to permit large amounts of the contronting areas of said front panel and of said rear panel to be moved apart to accommodate the body of a large infant, some of the longitudinally-distributed releasable fastener means of the first said releasable fastener means and some of the longitudinally-distributed releasable fastener means of said complementary releasable fastener means being securable together to reduce the amounts of said confronting areas of said front and said rear panels which can be moved apart to accommodate the body of an infant and thereby enable said bunting to accommodate and closely confine the body of an infant of smaller girth, some of the laterallydistributed releasable fastener means of the first said releasable fastener means and some of the laterally-distributed releasable fastener means of said complementary releasable fastener means being securable together to reduce the amounts of said confronting areas of said accommodate the body of an infant and thereby enable said bunting to accommodate and closely confine the body of an infant of shorter height, whereby the first said releasable fastener means and said complementary releasable fastener means enable said bunting to ac- 25 commodate and closely confine the bodies of infants of differing girths and differing heights.

7. The infant bunting of claim 1 wherein zippers selectively connect and free the edges of openings in said enclosure, wherein said zippers have electrostati- 30 cally conductive zipper bindings, wherein said enclosure has electrostatically conductive cloth strips, and wherein said electrostatically conductive zipper bindings and said electrostatically conductive cloth strips are in communication electrostatically with a central conductive tab to permit grounding of the bunting to the operating table by placing said central conductive tab in engagement with said operating table.

8. The infant bunting of claim 1 wherein said front portion of said enclosure is subdivided into two sides, wherein each of said two sides is selectively movable to an open position wherein it is spaced away from the corresponding side of the front of the body of an infant disposed within said enclosure to permit medical 45 procedures to be carried out on said corresponding side of said front of said body of said infant, wherein each of said two sides is selectively movable to a closed position wherein it is in intimate contact with the corresponding side of said front of said body of said infant, 50 and wherein adjustable releasable circumferential fastener tabs span the opened side of said bunting during medical procedures thereby maintaining the closed side of the bunting in intimate contact with the cor-

9. An infant bunting for enclosing the body of an infant and for controlling the body temperature of said infant comprising an enclosure which is made of stretch fabric that is stretchable in at least the lateral direction, said enclosure having a front panel disposable in register with the front of the body of an infant and having a rear panel disposable in register with the rear of said body of said infant, said front panel and said rear panel being sized to enable said enclosure to accommodate the body of a large infant with only limited stretching of said stretch fabric in said lateral direction, fluid-conveying tubing secured to said front panel of said enclo-

sure in a pattern distributing said fluid-conveying tubing over substantially the entire surface of said front panel of said enclosure that contacts said front of said infant's body to confine and guide heat-exchanging fluid for movement in heat-exchanging relation with respect to said front of said infant's body, further fluidconveying tubing secured to said rear panel of said enclosure in a pattern distributing said further fluid-conveying tubing over substantially the entire surface of said rear panel of said enclosure that contacts said rear of said infant's body to confine and guide heatexchanging fluid for movement in heat-exchanging relation with respect to said rear of said infant's body, the first said fluid-conveying tubing including a plurality of individual tubes that have supply spans and return spans, said plurality of individual tubes of the first said fluid-conveying tubing being disposed so the supply and return spans of the first said fluid-conveying tubing front and said rear panels which can be moved apart to 20 alternate to provide uniform temperature distribution over substantially the entire surface of said front panel of said enclosure that contacts said front of said infant's body, said further fluid-conveying tubing including a further plurality of individual tubes that have supply spans and return spans, said further plurality of individual tubes of said further fluid-conveying tubing being disposed so the supply and return spans of said further fluid-conveying tubing alternate to provide uniform temperature distribution over substantially the entire surface of said rear panel of said enclosure that contacts said rear of said infant's body, supply manifold means to supply heat-exchanging fluid to said supply spans of said plurality of individual tubes of the first said fluid-conveying tubing and to said supply spans of said further plurality of individual tubes of said further fluid-conveying tubing, return manifold means to receive heat-exchanging fluid from said return spans of said plurality of individual tubes of the first said fluidconveying tubing and from said return spans of said further plurality of individual tubes of said further fluid-conveying tubing, a plurality of individual and discrete releasable fasteners secured to said front panel of said enclosure and spaced longitudinally and laterally of said front panel of said enclosure, said plurality of releasable fasteners being spaced inwardly from the side and bottom edges of said front panel of said enclosure, a plurality of complementary individual and discrete releasable fasteners secured to said rear panel of said enclosure and spaced longitudinally and laterally of said rear panel of said enclosure, said complementary plurality of releasable fasteners being spaced inwardly from the side and bottom edges of said rear panel of said enclosure, the releasable fasteners of the responding side of said front of said body of said infant. 55 first said plurality of releasable fasteners being in register with and being selectively securable to and releasable from the releasable fasteners of said complementary plurality of releasable fasteners, the releasable fasteners of the first said plurality of releasable fasteners and the releasable fasteners of said complementary plurality of releasable fasteners being releasable from each other to permit a large amount of the area of said front panel of said enclosure to be moved far enough away from a corresponding amount of the area of said rear panel of said enclosure to enable said bunting to accommodate but confine the body of said large infant, some of the longitudinally-spaced releasable fasteners of the first said plurality of releasable fasteners and some of the longitudinally-spaced releasable fasteners of said complementary plurality of releasable fasteners being securable together to reduce the amounts of said confronting areas of said front and 5 said rear panels which can be moved apart to accommodate the body of an infant and thereby enable said bunting to accommodate and closely confine the body of an infant of smaller height, some of the laterally spaced releasable fasteners of the first said plurality of 10 releasable fasteners and some of the laterally-spaced releasable fasteners of said plurality of complementary releasable fasteners being securable together to reduce the amounts of said confronting areas of said front and said rear panels which can be moved apart to accom- 15 modate the body of an infant and thereby enable said bunting to accommodate and closely confine the body of an infant of shorter girth, whereby the releasable fasteners of the first said plurality of releasable of complementary releasable fasteners enable said bunting to accommodate and closely confine the bodies of infants of differing heights and differing girths, said some of the laterally-spaced releasable fasteners of the first said plurality of releasable 25

fasteners and said some of the laterally-spaced releasable fasteners of said plurality of complementary releasable fasteners coacting to provide a coarse size adjustment for said enclosure in the lateral direction, the stretchable nature of said stretch fabric of said front panel and of said rear panel of said enclosure enabling said front panel and said rear panel of said enclosure to provide a fine size adjustment for said enclosure in the lateral direction, and a pressure-distribution liner that is releasably fastened to said rear panel, said pressuredistribution liner overlying said tubes of said further fluid-conveying tubing to distribute evenly to said body of said infant the forces which said tubes of said further fluid-conveying tubing otherwise would distribute unevenly to said body of said infant, said pressure-distribution liner having openings therein in register with said releasable fasteners of the first said plurality of releasable fasteners and in register with said releasable fasteners of said complementary plurality of releasable fasteners and said releasable fasteners of said plurality 20 fasteners to permit securement of said releasable fasteners of the first said plurality of releasable fasteners to said releasable fasteners of said complementary plurality of releasable fasteners through said openings.

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## United States Patent [19]

Augustine et al.

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# [54] AIRFLOW COVER FOR CONTROLLING BODY TEMPERATURE

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[21] Appl. No.: 586,554

[56]

[22] Filed: Mar. 5, 1984

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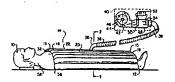
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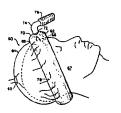
Primary Examiner—Anton O. Oechsle Attorney, Agent, or Firm—Brown, Martin & Haller

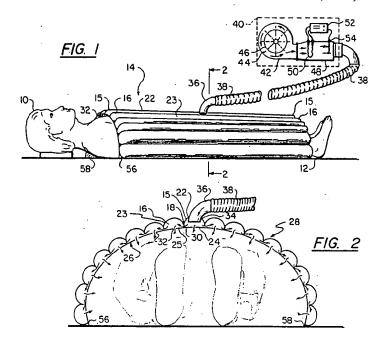
#### [7] ABSTRACT

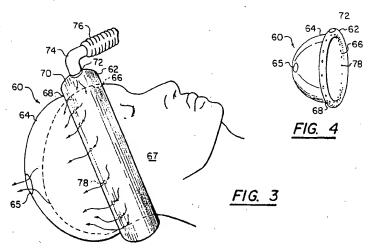
An airflow cover for controlling the body temperature of a patient covers a portion of the patient's body and provides a generalized thermal bathing of the covered portion through the delivery of a temperature controlled gas mixture to the covered portion. The cover is formed from a series of inflatable tubes which are joined together in a parallel array having an upper surface facing away from the patient's body and an oppositely directed lower surface which faces the covered portion of the patient's body. An entry port is provided through the upper surface and into one tube, transverse ports open between the tubes, and exit ports are formed in the lower surface. A thermally controlled gas mixture is introduced through the entry port, circulates in the tubes, and exits through the exit ports and inflates the tubes, and exits through the exit ports in the direction of the covered body portion to provide the desired thermal bathing.

10 Claims, 4 Drawing Figures









#### AIRFLOW COVER FOR CONTROLLING BODY TEMPERATURE

#### BACKGROUND OF THE INVENTION

The cover of the invention relates generally to a cover used in a medical treatment environment to control the bodily temperature of a patient, and more specifically to such a cover which controls the temperature of a covered patient's body by bathing it with a temperature controlled gas mixture

It is often the case that the bodily temperature of a patient who is about to undergo or who has undergone certain forms of medical treatment such as surgery must be regulated by lowering or elevating it to a predetermined average level. In existing apparatus, the generalized control of such a patient's temperature is provided by means of a pliable blanket through which a tempera-ture controlled fluid is circulated. When the patient is covered with such a blanket, the temperature of the 20 fluid is conducted to the patient to move the patient's temperature toward the desired level. However, most of the temperature exchange between the blanket and the patient takes place only at the points where the blanket contacts the patient's skin. This can result in 25 localized thermal activity of a high rate where the blanket and the patient's skin are in contact, which results in the localized temperature of the contacted portion of the patient's body being either substantially above or below the desired average temperature. When the pa- 30 tient's body temperature is being elevated and the circulating fluid is heated, this can result in burning at the contacted areas. In addition, the heat transfer between the blanket and the portions of the patient's body which the blanket does not contact is radiative and therefore 35 inefficient.

In other covers, the circulating heat transfer mechanism is temperature controlled air. In one such cover disclosed in U.S. Pat. No. 2,110,022, the air is circulated inside of a flexible bag which has a top insulating layer 40 and a bottom heat conducting layer which contacts the patient. However, the structure of this blanket makes it unnecessarily heavy and rigid. The weight of the blanket can press its inner surface against the covered patient and block a number of the exit ports, thereby re- 45 ducing the total body area over which the air circu-

It is therefore desirable to provide a supple, lightweight cover for efficiently and effectively controlling the bodily temperature of a covered patient.

#### SUMMARY OF THE INVENTION

The cover of the present invention overcomes the limitations of existing covers which control the bodily temperature of the patient by providing a lightweight 55 flexible, inflatable casing having an upper and a lower surface. The casing has an entry port penetrating its upper surface for permitting a thermally-controlled inflating medium to flow into and inflate the casing, and a plurality of exit ports formed in the lower surface for, 60 when the casing is inflated, permitting the thermallycontrolled medium to flow out of the casing's lower surface. The cover is placed over a patient and inflated by introduction of the medium through the entry port into a self-supporting structure which encloses the pa- 65 tient. The temperature-controlled inflating medium circulates through the inflated casing and exists through the exit ports on the lower surface which faces the

patient to provide the desired generalized thermal bathing of the patient's body.

Preferably, the casing is made from a plurality of enlongated inflatable tubes, each of which is formed from a lightweight flexible material such as plastic. The tubes are joined together longitudinally to form a substantially parallel array, the opposing major surfaces of which form the upper and lower surfaces of the cover. An entry port is provided in the upper surface; transverse ports are provided between adjoining tubes; and a plurality of exit ports are provided in the lower surface of the array. The tubular structure of the cover and the material from which the tubes are formed enable the casing to inflate and to form a self-supporting structure when the cover is laid atop the patient. The tubular construction causes the cover to naturally wrap around the patient and provide a semi-enclosed, generally tubular structure which covers the patient. The inflating medium is preferably a gas mixture which is provided under pressure from a unit which exchanges energy with the mixture. The light weight of the casing permits it to be partially supported by the air escaping through the exit ports which prevents the cover from blocking the ports by contacting the covered body portion.

The unit is connected to the input port by means of a delivery hose and has a blower assembly for forcing the mixture into the cover. In the preferred embodiment, the gas mixture constitutes ambient air which is heated to a desired temperature level and blown through the delivery hose to the cover and delivered therefrom through the exit ports to thermally bathe the patient.

It is therefore the principal object of the present invention to provide an airflow cover which controls the body temperature of a patient by delivering a diffused flow of a thermally-controlled gas mixture which results in a generalized thermal bathing of the patient.

It is a further object of the present invention to provide such a cover which is inflated by the temperaturecontrolled mixture into a self-supporting structure which substantially encloses the patient and thereby increases the efficiency of the generalized thermal bath-

Other objects and advantages of the present invention will become apparent when the description of the preferred embodiment is read in conjunction with the following drawing figures:

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of the airflow cover of the invention in a representative operational environment. FIG. 2 is a partial sectional view of the cover of the invention with the cross section of the cover taken along lines 2-2 of FIG. 1.

FIG. 3 is an illustration of a representative application environment for a second embodiment of the airflow cover of the invention where the cover is used to thermally bathe a portion of a patient's body.

FIG. 4 is a perspective view of the embodiment illustrated in FIG. 3.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

With reference to FIG. 1, the reader will understand the operational application of the preferred embodiment of the air-flow cover of the invention. In FIG. 1 a patient 10 is shown reclining on a surface which may comprise the upper surface of a gurney or a bed. Surrounding the patient is the cover of the invention, illustrated generally by 14, which is shown placed over the patient and inflated into a substantially semi-tubular structure which encloses the major portion of the patient's midbody. In the illustrated operational application, the cover-14 is delivering a diffused stream of heated air by means disclosed in greater detail hereinbelow to the enclosed portion of the patient's body. Such an application would be useful, for example, where the patient's temperature has dropped below a medically safe average to a point where a peril of hypothermia is presented. In such a circumstance, it is desired to quickly and efficiently raise the patient's temperature in order to restore the temperature to as near normal as is

3

The means by which the cover 14 accomplishes the desired purpose can be understood with reference to FIGS. 1 and 2. The cover 14 is made up of a plurality of parallel elongate plastic tubes, two of which are indi-cated by 15 and 16, interconnected to form an inflatable casing. It is to be understood that the description of the tube 16 precisely describes the remaining tubes which form the cover. As illustrated, the tubes 15 and 16 are joined together by a intermittent longitudinal seam 18. Each tube is formed from a flexible inflatable material, 25 such as plastic. The use of plastic to form the tubes 15 and 16 permits the seal 18 to consist of either a heat seal or a cured epoxy seal which is sufficient to join the tubes as indicated. The tubes 15 and 16 have halfrounded cross-sectional shapes with rounded upper 30 portions 22 and 23, respectively, and flattened lower portions 24 and 25, respectively. The lower flattened portions of all of the joined tubes together form a lower surface 26 and the rounded upper portions, a generally longitudianlly quilted upper surface 28.

One or more transverse openings or ports 30 are provided through the seam 18 and through all of the seams to permit an inflating medium such as air to circulate between the tubes. A plurality of exit ports 32 are provided in the lower flattened portions of all of the 40 tubes which permit the circulating medium to flow out of the tubes and through the lower cover surface 26. Although the ports 30 and 32 are shown aligned in FIG. 2, it should be evident that they may be alternately staggered into the plane of the cross section so that the illustration would then show alternate tubes with ports, the ports of the non-ported tubes being out of the plane of the section. A single input port 34 in the keystone tube 15 accepts the end nozzle 36 of a delivery hose 38, which is connected to a heater/blower assembly 40. The assembly includes a blower housing 42, a fan 44, and a motor 46 which is coupled to rotate the fan 44. The housing 42 is connected to and communicates with a heating manifold 48 in which is disposed a heating element 50 connected to a standard temperature controller 52. A thermistor probe 54 is also disposed in the manifold 48 between the heating element 50 and the end of the delivery hose 38.

In operation, the heater/blower assembly 40 causes air heated to a predetermined temperature to be blown 60 through the delivery hose 38 and the nozzle 36 into the keystone tube 15 of the cover 14. The temperature-controlled air circulates from the keystone tube 15 through the transverse ports 30 into all of the other tubes which form the cover 14. The heater/blower 40 is operated to 50 provide an input flow of heated air which has sufficient pressure to fully inflate all of the tubes of the cover 14 without causing any of them to burst. As the heated air

flows into the tubes and inflates them, the inflation pressure causes the heated air to be forced out of the exit ports 32. The air which is blown from the exit ports 32 provides the generalized thermal bathing of the patient 10. The arrows in FIG. 2 indicate the direction of circulation of the air from the delivery hose 38 through the cover 14 to the patient 10. When the cover 14 is placed over the patient 10 and inflated, the pressure of one tube against another is collected at the edges 56 and 58 of the cover which causes the edges to curl down around the patient toward the surface 12. However, the inflation of the tubes provides the cover 14 with a selfsupporting structure having a generally rounded or elliptical cross-sectional shape which contacts the patient 10 only at the tubes which are immediately adjacent the keystone tube 15. The lightweight material from which the tubes are formed permits the air pressure which is exerted through the exit ports 32 of those tubes which are in contact with the patient to raise those tubes slightly so that circulation is provided through those exit ports. This is in contrast with the heavy structures of the existing airflow covers whose weight and structure block the ports which contact the patient. The cross-sectional structure illustrated in FIG. 2 enables the cover 14 to diffuse the temperature-controlled air which is delivered through the hose 38 into a generalized airflow which bathes as much of the patient's body as is covered by the cover 14. This convective operation increases the effectiveness and efficiency of the thermal exchange between the patient and temperaturecontrolled air without causing the localized thermal exchange of the existing circulating water blankets.

An alternate embodiment of the airflow cover of the invention is illustrated in FIGS. 3 and 4 wherein a scalp air-flow cover 60 includes an inflatable annular tube 62 to which is joined a generally rounded cap or enclosure 64 having an exit port 65. The annular tube has an inner surface 66 forming an opening which is placed over a portion of the head of a patient 67. Both the tube 62 and the cap enclosure 64 are constructed from a lightweight, flexible material, such as thermally-formed sheet plastic. The two pieces are joined by a continuous air-tight seam 68. The annular tube 62 has an outer surface 70 through which a port 72 is provided which accepts the nozzle 74 of a delivery hose 76. The delivery hose 76 is connected to a heater/blower assembly (not shown) which is identical in all respects to the heater/blower assembly 40 of FIG. 1. On the inner surface 66 of the annular tubes 62 and adjacent the seam 68, a plurality of exit ports 78 are provided. The exit ports are formed in the tube to be on the interior of the heating cap 60 when it is placed on the head of the patient 61. In operation, when pressurized or flowing air is introduced through the delivery hose 76, the annular tube 62 is inflated, with the inflating air being forced under pressure out of the exit ports 78. When the tube 62 is inflated it forms a contact barrier between itself and the head of the patient 67 so that air which flows out of the exit port 78 is forced into the end portion 64, circulates therein and exits through the end portion exit port 65. Thus, the annular tube 62 diffuses the flow of air delivered by the hose 76, with the tube and the end portion 64 providing a generalized thermal bathing of the scalp and head of the patient 67. It should be evident that when the tube 62 inflates, it slightly raises the head of the patient 67, thereby providing an air passage between the lower portion of the patient's head and the end portion 64. It should be further evident that this

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5 maximizes the area of the patient's scalp which is thermally bathed.

Although the embodiments of the invention are described as operating in conjuction with heated air, it should be evident to those skilled in the art that a source of pressurized cooled air will provide a generalized cooling bath using either of the cover embodiments described hereinabove to control the body temperature of the patient under conditions of hyperthermia. More- 10 over, it should be evident that, while the inflating and bathing mixture was described as heated air, any medium which is sufficiently vaporized can be used to inflate either embodiment of the cover and to provide the generalized thermal bathing. Moreover, it is possi- 15 ble to suspend an aerosal in the inflating and circulating medium, which can include a disinfectant for treatment of burned areas of the patient's body.

Obviously, many modifications and variations of the 20 described embodiments are possible in light of the above teachings, and it is therefore understood that the invention may be practiced otherwise than as specifically described.

We claim:

1. A cover for delivering a diffuse medium flow to a human body, comprising:

an inflatable cover housing including a plurality of inflatable hollow tubes, each tube having a 30 rounded upper portion and a flattened lower portion, joined in a substantially parallel array to form a substantially smooth lower cover surface including said lower tube portions for facing a body to be covered and a quilted upper cover surface includ- 35 ing said upper tube portions for facing away from said body:

an entry port in said upper surface for admitting an inflating medium into said housing;

transverse openings connecting the interior of each 40 tube with the interior of at least one other adjacent tube in said array for conducting an inflating medium into all of said tubes to inflate said housing;

said tubes for, when said housing is inflated, permitting said medium to flow out of said housing through said smooth lower surface.

2. The covering of claim 1 further including a source of a thermally controlled, inflating meduim connected to said entry port means.

3. The covering of claim 2 wherein said medium comprises a gas mixture.

4. The covering of claim 3 wherein said gas mixture comprises air.

5. The covering of claim 1 wherein, when said housing is inflated and placed over a body, said housing assumes a tubular, self-supporting structure for substantially enclosing said body.

6. The covering of claim 1 wherein each said exit

opening is substantially smaller than said entry opening.

7. The covering of claim 6 further including a source of a pressurized, thermally controlled gas mixture connected to said entry port means, wherein said thermally controlled gas mixture enters said array through said entry port, inflates said housing, and flows out from said inflated housing through said exit ports.

8. A cap for controlling the temperature of the head of a reclining person, comprising:

an inflatable annular tube forming a central opening for encirclingly fitting to the head of a person reclining on a support surface and for being inflated to lift said head from said surface;

a sheet of material attached to one side of said annular tube over said central opening to form a recess for receiving substantially the top of a head when said head extends into said recess through said central opening:

an outer surface on said tube;

an entry port on said tube outer surface for admitting a temperature-controlled, inflating medium into. said tube:

an inner surface in said tube's central opening;

exit ports in said inner surface for, when said tube is inflated with an inflating medium, conducting said inflating medium from said tube into said recess;

an exit port, substantially smaller than said central opening, in said material sheet for venting an inflating medium from said recess to an external environ-

9. The cap of claim 8 further including a source of exit ports formed in the flattened portion of each of said entry sort

10. The cap of claim 9 wherein said medium comprises a gas mixture.

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## United States Patent [19]

### Greene, Jr.

[11] Patent Number:

4,660,388

Date of Patent:

Apr. 28, 1987

[54]	COOLING	COVER
[76]	Inventor:	George J. Greene, Jr., 616 N. Eldridge St., Houston, Tex. 77079
[21]	Appl. No.:	780,280
[22]	Filed:	Sep. 26, 1985
	Relat	ted U.S. Application Data
[63]	Continuation 1984, abando	n-in-part of Ser. No. 613,913, May 24, oned.
[58]		irch
[56]		References Cited

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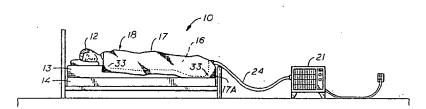
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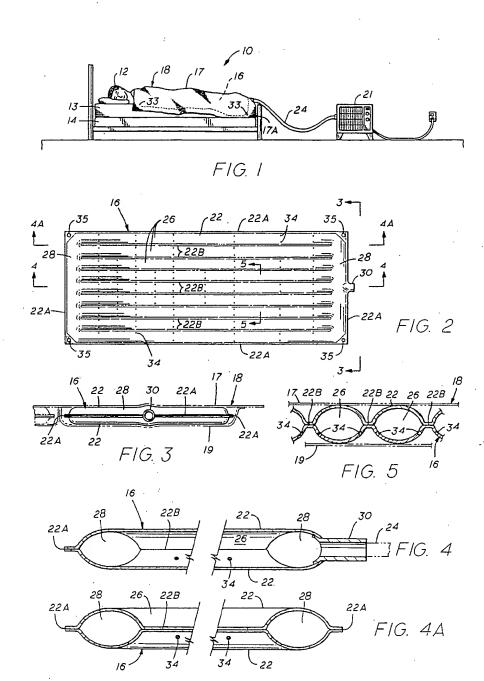
Primary Examiner—William E. Wayner Attorney, Agent, or Firm—Vinson & Elkins

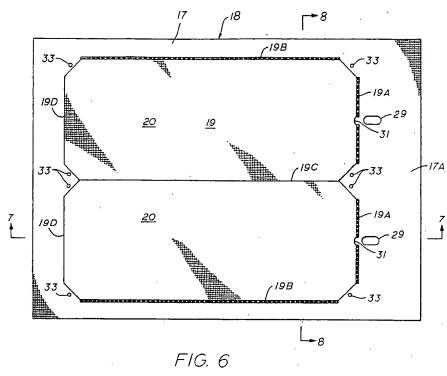
### ABSTRACT

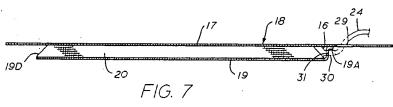
A cooling cover (10) has an air inflatable pad (16) which may be positioned within a pocket (20) of a coverlet (18). The pad (16) formed of air impermeable material has plenum chambers (28) at opposite ends thereof, and a plurality of individual longitudinally extending passing a control of the page (28). sages (26) extend between the plenum chambers (28). Openings or air orifices (34) of a non-uniform pattern in the lower rounded surfaces of the inflatable pad (16) direct cooling air in a plurality of small air jets onto the body of a user of the cooling cover (10). A source of cool air (21) is connected to the inlet (30) for a plenum chamber (28) to deliver cool air to the pad (16).

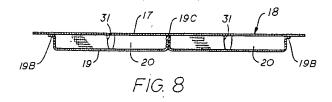
### 5 Claims, 9 Drawing Figures











#### CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of application Ser. No. 613,913 filed May 24, 1984.

#### BACKGROUND

Individual cooling suits and blankets have been at- 10 tempted to provide cooling of people. Much of the work on this type of equipment has been done in the design of suits to be worn in space. In these prior art devices, cooling is accomplished by circulating a cooling liquid through cooling coils in the suit and supplying cooling air to a helmet to assure the supply of a cool air for breathing and cooling of the individual's face. A typical example of this type of suit is disclosed in U.S. Pat. No. 4,095,593. A suit to be worn during operations in a hospital is shown in U.S. Pat. No. 3,738,367 and <sup>20</sup> includes tubes through which cooling liquid from a hyperthermia machine is circulated.

Another type of suit is shown in U.S. Pat. No. 3.174.300 which recirculates air by a blower carried in the suit through a carbon dioxide absorber and a coolant 25 tank. The garmet shown in U.S. Pat. No. 3,479,838 utilizes a reduced pressure to cause water to boil in order to provide body cooling. A heat treating garment is shown in U.S. Pat. No. 3,610,251 which flows hot air into a baglike garment having apertures in the wrist or 30 shoulders to allow escape of the hot air.

The R. S. Gaugler U.S. Pat. No. 2,093,834 discloses a

refrigerating apparatus which can be used as a bed cover or as a garment. The cooling air or treating medium is supplied to an enclosure formed of sheeting and 35 diffuses through the sheeting to cool the body of the individual under the apparatus.

None of these prior structures provide a simple structure which is suitable to cool an individual over a substantial portion of his body while he is asleep.

#### SUMMARY

The present invention provides a cooling cover to be used to cool an individual while sleeping or resting and includes a pad formed of an air impermeable material 45 defining an air distribution chamber. The air distribution chamber has a plurality of longitudinal passages extending between transverse plenum chambers at each end of the pad, and an air inlet connects to the plenum chamber at the foot of the pad. The longitudinally extending air passages are defined by lower rounded surfaces which have openings or apertures therein spaced from the body of an individual and arranged to direct cool air onto the individual in a jet action.

A preferred source of cool air is a refrigeration or air 55 conditioning system which includes a blower to cause the air to flow in heat exchange with the refrigeration system, and means for delivering the cooled air from the refrigeration system to the air distribution chamber inlet. A coverlet formed of a porous material has a 60 pouch or pocket to receive the pad and air discharged from the apertures of the distribution chamber is diffused slightly by the porous material of the coverlet to keep the cool air flow from impacting an objectionable jet streams on the body of a user. Although some diffusing of the jet stream is desirable, an important part of this concept of cooling is to rely heavily upon the velocity of the air stream to enhance the cooling effect,

thereby reducing the need for temperature depression and additional BTU cooling capacity.

An object of the present invention is to provide an improved cooling cover for a human body or individual which is effective for cooling the individual while sleeping or resting.

Another object is to provide an improved cooling cover for a human body which is relatively simple in construction, reasonable in cost, and can be operated with a portable power supply.

A further object is to provide an improved cooling cover for sleeping in hot environments which is efficlent by exposing the body skin to a meaningful air velocity, but at the same time does not expose the user to jets of uncomfortably cool air.

#### DESCRIPTION OF THE DRAWINGS

These and other objects and advantages are hereinafter set forth and explained with reference to the drawings wherein:

FIG. 1 is an elevational view, partly schematic, of the improved cooling apparatus of the present invention including an outer coverlet and an inner pad contained therein having an air distribution chamber.

FIG. 2 is a view of the underside of the inner pad forming the air distribution chamber of the present invention.

FIG. 3 is a elevational view of the inner pad taken along line 3-3 in FIG. 2.

FIG. 4 is a sectional view of the inner pad taken along line 4-4 in FIG. 2.

FIG. 4A is a sectional view of the inner pad taken along line 4A-4A in FIG. 2.

FIG. 5 is a sectional view of the inner pad taken along line 5-5 in FIG. 2 to illustrate the air distribution chamber apertures.

FIG. 6 is a plan of the underside of the outer coverlet having pockets to receive the pads.

FIG. 7 is a sectional view of the coverlet taken along line 7-7 of FIG. 6 with the inner pad shown in broken

FIG. 8 is a sectional view of the coverlet taken along line 8-8 of FIG. 6.

#### BRIEF DESCRIPTION OF THE PREFERRED EMBODIMENT

The improved cooling cover of the present invention is indicated generally at 10 in FIG. 1 covering an individual or person 12 positioned on a mattress 13 of bed 14. Cooling cover 10 includes a pair of inner pads 16 positioned within an outer coverlet 18. Pads 16 form air distribution chambers and each pad 16 as shown in FIGS. 2-5 is preferably formed of an air impermeable heat bondable material such as polyethylene, polyvinylchloride, or other similar material.

Outer coverlet 18 as shown in FIGS. 6-8 includes an outer sheet 17 which may be formed, if desired, of an air permeable or porous material such as cotton; and an inner spaced sheet 19 which is always formed of an air permeable or porous material. Inner sheet 19 which is normally placed adjacent the body of a user is secured at one end 19A, sides 19B and intermediate portion 19C to sheet 17. The other end 19D of sheet 19 is open and spaced from sheet 17 thereby to define a pair of identical porous pockets or pouches 20 arranged in side-byside relation. Each pouch 20 receives an inner pad 16 within open end 19D. A source of cool air such as cool air generator 21 is connected to a flexible hose or conduit 24 and has a suitable blower for delivering cool air to inner pads 16.

Each inner pad 16 which forms the air distribution chamber as shown in FIGS. 2, 3 and 4, is formed of two 5 sheets of air impermeable material 22 as set forth above which are bonded together at their outer edges 22A. Also, intermediate portions 22B are suitably joined, as by bonding, to form a plurality of longitudinally extending air passages 26 extending from transversely extending plenum chambers 28 at each end. An air inlet 30 is positioned at the end of each pad 16 in communication with plenum chamer 28 to supply air to air passages 26.

Coverlet 18 has an end marginal portion 17A which extends beyond upper sheet 19 and beyond porous 15 pouches 20 in which inner pads 16 are positioned. End portion 17A may be folded under the feet of individual 12 or be tucked under mattress 13 on bed 14 to provide a selective positioning of pads 16 and the air distribution chambers thereof on the individual. Coverlet 18 has 20 suitable openings 29 and 31 to receive flexible hose 24 for connection to inlet 30 thereby to provide cool air to air passages 26 from cool air generator 21. Snap fasteners 33 on outer sheet 17 may engage interfitting fasteners 35 on pads 16 to hold pads 16 in place within pockets 25 20.

Each of the longitudinally extending air passages defines a lower rounded surface which is provided with a plurality of apertures 34 positioned as best shown in FIG. 5 so that the resting of inner pad 16 on the individ- 10 ual does not block the flow through any of the apertures 34 since apertures 34 are spaced from the body of the individual. Inner pad 16 is inflatable and a generally uniform pressure is provided. A predetermined arrangement of apertures 34 which form air orifices for pad 16 35 directs the air to predetermined areas of the body. Thus, a non-uniform distribution of apertures 34 permits a relatively-high cooling efficiency.

It has been discovered that the jetting of the cool air through the apertures 34 at a velocity of not less than 40 thirty feet per second results in very substantially improved cooling as compared to air diffusion through a sheet or cover. Also, each pad 16 would have approximately one hundred (100) one-eighth inch diameter apertures 34.

Further, it has been found that a cooling capacity of cool air generator 21 should be approximately 650 BTU/hour per person being cooled. This will provide an ambient air cooling at the source between 20° and 25° F, with a reduction of 18° F, at the body of the individual for cooling with ambient air temperature above 90° F. The air flow onto an individual is preferred to be in the range of 20 to 35 cubic feet per minute. A pressure of 0.4 to 0.9 inches of water is maintained in pad 16 to control the optimum air velocity and to support the 55 shape of pad 16. An electric power consumption of between 130 and 175 watts per person allows a 300 to 350 watt generator to service a double unit as shown in F1G. 6.

It is suggested that the evaporator coil in the cool air 60 generator be located above the vertical midpoint of the condenser unit so that gravity causes condensed moisture from the evaporator coil to flow to the hot condenser coil for evaporation and thus to increase the efficiency of the unit under high humidity conditions.

While the preferred embodiment of coverlet 18 is illustrated in FIGS. 6-8 as having a pair of pouches 20 for a pair of pads 16. it is to be understood that a single

pad 16 and single porous pouch 20 could be provided if desired.

While preferred embodiments of the present invention have been illustrated in detail, it is apparent that modifications and adaptations of the preferred embodiments will occur to those skilled in the art. However, it is to be expressly understood that such modifications and adaptations are within the spirit and scope of the present invention as set forth in the following claims.

What is claimed is:

1. A generally rectangular cooling cover adapted to be positioned over a human body in a prone position; said cooling cover comprising;

a coverlet having an outer sheet, an inner porous pouch attached to the outer sheet, and an inner pad within the porous pouch:

said inner pad including a pair of upper and lower sheets formed of an air impermeable material with the upper sheet adjacent the coverlet and the lower sheet adjacent the porous pouch, said sheets secured to each other along their outer edges to form an air distribution chamber therebetween, and secured to each other along a plurality of parallel intermediate portions extending lengthwise between the ends of the sheets for a major portion thereof to form a plurality of separate longitudinally extending air passages there-between having lower rounded surfaces, a plenum chamber extending transversely of the pad at each end thereof in fluid communication with said longitudinally extending air passages; and

a cool air inlet at one end of said inner pad, said coverlet having an opening therein in alignment with said inlet of said pad adapted to receive a source of cool air for connection to said inlet;

said lower rounded surfaces having a plurality of apertures along the length thereof at locations other than the lowermost portion of said rounded surfaces and in fluid communication with said longitudinally extending passages whereby cool air may be discharged as small jets through said apertures at an angular relation to a vertical plane for diffusing through the porous pouch to contact a large area of the body cooled.

 A cooling cover as set forth in claim 1 wherein said outer sheet of said coverlet has fasteners thereon adjacent the corners of said pad, and said pad has interfitting fasteners thereby to releasably secure said pad within the pocket of said coverlet.

3. A cooling cover as set forth in claim 1 wherein said outer sheet of said coverlet and said pouch have aligned openings therein adapted to receive a flexible hose from said source of cool air for connection to said cool air inlet of said pad, thereby to supply cool air to said pad.

4. A cooling cover as set forth in claim I wherein said upper and lower sheets of said inner pad are formed of heat bondable plastic material.

5. Air conditioning means for a human body compris-

a general rectangular cooling cover adapted to be positioned over the human body in a prone position, said cooling cover including a coverlet having an outer sheet, an inner porous pouch attached to the outer sheet, and an inner pad within the porous pouch; said inner pad including a pair of upper and lower sheets formed of an air impermeable material with the upper sheet adjacent the coverlet and the lower sheet adjacent said porous pouch, said sheets

5 secured to each other along the outer edges to form an air distribution chamber therebetween, and secured to each other along a plurality of parallel intermediate portions extending lengthwise between the ends of the sheets for a major portion 5 thereof to form rounded surfaces defining a plurality of searche longitudinally extending air received. ity of separate longitudinally extending air passages;

sages;
a plenum chamber extending transversely of said pad
at each end thereof in fluid communication with 10
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rounded surfaces having a plurality of apertures
therein for discharging cool air therethrough as
small jets for diffusing through the air permeable
porous pouch for contacting the human body, said 15

apertures being arranged in a non-uniform manner with air being discharged therefrom at a velocity in

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a range between 30 and 50 feet per second; a cool air inlet at one end of said inner pad in fluid communication with the associated plenum chamber at said one end, said coverlet having an opening adjacent said cool air inlet;

a source of cool air; and means extending through said opening in said cover-let to said inlet to connect the source of cool air to said air inlet for inflating the inflatable pad and providing air to said apertures for discharge there-from, said source of cool air having a capacity of approximately 650 BTU/hour per person.

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Sandhaus

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[11] Pa Number:

4,807,644 Feb. 28, 1989

[45] Date of Patent:

123/132 D

[54]	TEMPERATURE-REGULATING SURGICAL DRAPE					
- [75]	Inventor:	Jeffrey J. Sandhaus, Astoria, N.Y.				
[73]	Assignee:	Vastech Medical Products Inc., New Brunswick, N.J.				
[21]	Appl. No.:	13,773				
[22]	Filed:	Feb. 12, 1987				
[51] [52] [58]	U.S. Cl Field of Sea					
[56]	•	References Cited				
	U.S. PATENT DOCUMENTS					
	3,763,857 10/1	1965       Caillouette       128/403         1973       Schrading et al.       128/132 D         1976       Watson et al.       128/403 X				

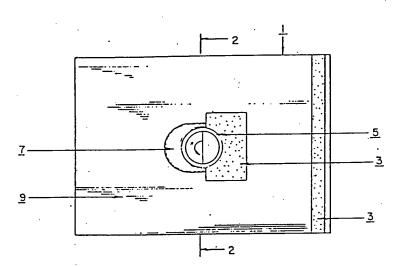
4 413 624	11/1983	Stoneback	123/402	Х

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Krumholz & Mentlik

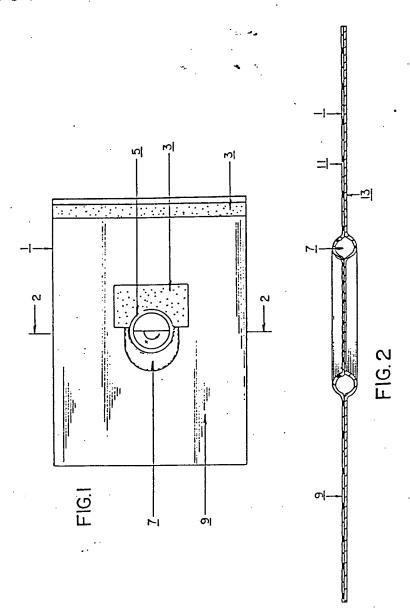
[57] ABSTRACT

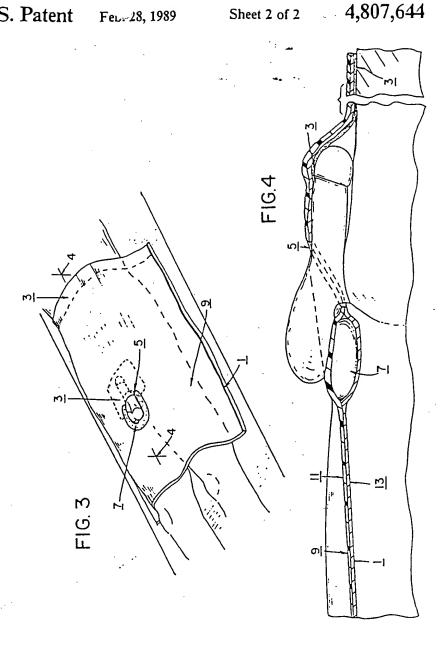
Temperature regulating surgical drapes are disclosed for use in conducting surgical procedures including a drape body with an opening adapted to expose only the specific body portion during surgery and including hear generating or cooling elements affixed to the drape at a localized position surrounding the opening to maintain that body portion at a specified temperature during surgery.

28 Claims, 2 Drawing Sheets









#### 2

## TEMPERATURE-REGULATING SURGICAL DRAPE

### FIELD OF THE INVENTION

This invention relates generally to fenestrated surgical drapes, temperature-regulating surgical devices, and more specifically, to self-warming or self-cooling surgical drapes for use in scrotal surgery.

#### BACKGROUND OF THE INVENTION

Most surgical procedures require the use of fenestrated drapes which allow the surge ion access to the appropriate body region while simultaneously covering the rest of the body. The use of surgical drapes is not confined to humans. They are frequently used in animal surgery whenever it is desirable to cover all of the body save the operating field. Such drapes today are usually disposable and water repellant. They can be attached to the body by adhesive to prevent sliding during surgery.

20 Drapes of this sort are usually best-suited to use on relatively flat, smooth portions of the body such as the abdomen.

In performing vasectomy procedures the surge ion operates on the patient's scrotum. Such procedures present special surgical problems. The male reproductive organs' shapes are not ones to which surgical drapes readily conform. The scrotum tends to thicken and contract when cooled during exposure. This causes the testes and sperm ducts to move upward toward the groin, making surgery in this region difficult. Scrotal surgery is normally performed with the patient lying on his back and his penis placed against his abdomen with its lower surface facing upward. This is not a stable position and the penis frequently enters into the surgical 35

Fenestrated surgical drapes are manufactured with openings which allow access to the surgical field. They can be produced in a variety of forms and with a variety of sizes and shapes of surgical openings. Normally the 40 surgical drape is placed above the surgical zone. When operating on irregularly shaped regions it may be advantageous to position the drape in a different manner. It is suggested that when surgery is performed in the scrotal region the scrotum be passed through a hole in 45 the drape and placed above the drape. This orientation has two benefits; it isolates the scrotum from the body, and it locates the penis under the drape so as to keep if from intruding into the field of surgery.

The scrotum contracts or relaxes in reaction to 50 changes in temperature. When cooled, it contracts and its surface thickens, pulling the testes and sperm ducts upward toward the body. Such changes make surgery more difficult and so it is desirable to keep the scrotum warm to encourage the desirable relaxation response. 55 Presently, surgical aids for maintaining a desired temperature include heat lamps, electrical heating pads, and sterile wet toweling. All require the use of expensive reuseable equipment, which must be sterilized before later use and which can clutter or obstruct the surgical 60 field.

Pouchlike heating or cooling devices containing separated chemical reactants, which only change temperature when manipulated so as to mix those reactants by repturing at least one internal pouch are admittedly 68 well-known in the art. See, for example: U.S. Pat. Nos. 4,080,953 (Mitchell); 3,854,156 (Williams); and 3,175,558 (Cailouette). Similarly, fenestrated surgical

drapes are well-known; see U.S. Pat. No. 4,316,456 (Stoneback). Williams, the closest to these patents to the instant invention, teaches only the use of a chemically-activated temperature regulating device in a combination mattress and blanket for transporting infants. It does not contemplate use in surgery. The now-expired Cailouette patent teaches the use of a chemically-activated temperature-regulating pack surrounded by a disposable outer cover, but does not contemplate use in surgery. The present invention successfully combines the temperature-control function of the already-known thermal pouches with the field-isolating function of surgical drapes in a low-cost, disposable structure, while simultaneously facilitating unimpeded access to the surgical field.

The present invention solves both the problems of scrotal contraction and intrusion of the penis into the surgical field.

# OBJECTS AND STATEMENT OF THE INVENTION

It is therefore an object of the present invention to provide a surgical drape which allows maintenance of the surgical field within a preselected temperature range.

It is another object of the present invention to provide a surgical drape which will permit maintenance of the scrotum within a preselected temperature range.

It is a further object of the present invention to provide a surgical drape which, while isolating and exposing the scrotum, serves to keep the penis from intruding into the surgical field.

In one advantageous embodiment of an apparatus employing the instant invention, the temperature control and restraining functions are achieved by providing the following. A multilayered surgical drape with a centrally located opening of size slightly larger than the scrotum is employed. A strip of suitable adhesive runs along a portion of the perimeter of the lower surface of the drape. Another strip may be located adjacent to the edge of the drape's central opening. Both of these strips can be covered with plastic sheeting until use.

A thermal bag is fixably secured to the drape in such an orientation as to place its main portion nearest the patient's feet. The thermal bag lies underneath the patient's scrotum. The scrotum passes through the drape's opening and rests above the portion of the drape containing the thermal bag. The penis is kept out of surgical field (its top surface is held against the patient's abdomen,) and is medially located above the body and beneath the drape. The drape is further restrained by the aforementioned adhesive strips found on its lower surface.

The thermal bag attached to the drape is a flexible, leak-proof sack containing a primary reactant and a second smaller internal bag. The smaller internal bag is constructed such that vigorous bending or squeezing of the outer bag will cause the smaller internal bag to rupture. The internal bag contains a secondary reactant which, upon contact with the primary reactant disposed throughout the external bag, experiences either an exothermic or endothermic reaction which changes the temperature of the assembly. The primary and secondary reactants can be selected to cause the surgical field to achieve a temperature within a predetermined range. The aforementioned quality whereby vigorous bending or squeezing ruptures the internal bag but not the exter-

nal bag is called "manipulable rupturability." A manipulably rupturable bag must be constructed to protect against accidental rupture if dropped or mishandled, while not requiring undue effort to deliberately rupture the bag.

In another advantageous embodiment the drape's opening is constructed so that its perimeter elastically conforms to the portion of the scrotum passing through it. This facilitates isolating the surgical field.

In actual operation the drape is removed from its 10 sterile container and the bag is manipulated to break the internal bag, mixing the reactants and as a result of either an endothermic or exothermic reaction changing the bag temperature. The plastic sheeting covering the adhesive strips is removed and the fresh adhesive exposed. The drape is placed on the patient's torso; the penis is held under the drape against midline of the abdomen. The drape should be oriented so that the median of the bag is closest to the patient's legs. The scrotum is passed through the opening and placed atop the thermal bag.

Two advantages pertain to users of this invention. First, the scrotum can be kept warm by choosing reactants which, when combined, release heat. This will cause the scrotum to relax and descend, facilitating access to the organs therein.

Second, the penis will be kept from shifting into the operating field because it is held beneath the surgical drape, itself held immobile by the adhesive strips on its 30 lower side.

The foregoing objects, features and advantages of the present invention will become apparent from the following description of preferred embodiment in connection with the accompanying drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top elevational view of one embodiment of the present invention.

FIG. 2 is a cross-sectional view of one embodiment of 40 the present invention as seen along line 2-2 in FIG. 1.

FIG. 3 is a perspective view showing one embodiment of the present invention as used in surgery.

FIG. 4 is a cross-sectional view as seen along line 4-4 in FIG. 3.

#### DETAILED DESCRIPTION OF PREFERRED **EMBODIMENT**

Referring now to the drawings and, in particular, to FIGS. 1-4, there is depicted one embodiment of an 50 apparatus in accordance with the present invention.

A surgical drape assembly 1, having an opening 5, is located in the drape surface 9. Adhesive strips 3 are located on a portion of the underside of the drape surface 9. A thermal bag 7 containing a temperature regu- 55 lating means which is activated by selective manipulation of the thermal bag 7 is fixed about opening 5. The thermal bag 7 has the approximate shape of a semiannular section subtending an angle x about the center of a angle x being between 0 and 360 degrees. This shape is merely one of a myriad of other possible forms which will work equally well, such as discs, oblongs or polygons, either enclosing or adjacent to the opening 5. The thermal bag 7 is fixed between an upper drape surface 65 11 and a lower drape surface 13 as shown in FIG. 3. The thermal bag can also, if desired, be attached only to a surface of the drape 9.

4 The surgical drape assembly 1 is aligned so that the patient's scrotum passes through the opening 5 and rests upon the portion of the assembly containing the thermal bag 7. The patient's penis rests underneath the drape assembly 1 and is securely held by contact with a portion of an adhesive strip 3. Another adhesive strip 3 secures the drape assembly 1 to the patient's body. The scrotum, passing through the opening 5 rests on the upper drape surface 11 atop the thermal bag 7. The bag is fixably held between the upper drape surface 11 and th lower drape surface 13. One adhesive strip 3 attaches the penis to the lower drape surface 13 and another adhesive strip 3 attaches the lower drape surface to the patient's body.

The invention is employed using the following procedure: The thermal bag 7 is specifically manipulated so as to activate its termperature-regulating means. Such temperature-regulating bags are well known and often bag ("first bag") contains a primary reactant and an inner, rupturable bag ("second bag,") contains a second-ary reactant. The second bag breaks only after specific manipulation of the first bag. The reactants then mix and chemically combine in the still-intact first bag. The reactant are chosen so that the chemical reaction which results from their mixture causes the contents of the bag to reach from their mixture causes the contents to the bag to reach a preselected temperature and maintain that temperature for some period. Once the thermal bag 7 is specifically manipulated the scrotum is passed through the openings 5 and placed stop the upper drape surface 11 above the thermal bag 7. The adhesive strips 3 are pressed against the penis and body to keep the penis and drape from shifting.

It is also possible to use the instant invention in operations involving body parts other than the scrotum, whenever it is desirable to maintain the surgical field at a predetermined temperature.

Although a particular illustrative embodiment of the resent invention has been described herein, the present invention is not limited to this embodiment. Various changes, substitutions and modifications may be made thereto by those skilled in the art without departing from the spirit or scope of the invention defined by the appended claims.

I claim:

1. A temperature-regulating surgical drape for use in conducting surgical procedures on a predetermined body portion of a patient comprising a substantially planar drape body including an opening adapted to expose only said predetermined body portion during said surgical procedure, and means for generating heat affixed to said drape body at a localised predetermined location surrounding at least a portion of said opening for maintaining said predetermined body portion at a predetermined elevated temperature during said surgicai procedure.

2. The temperature-regulating surgical drape of claim 1 wherein said opening comprises a circular opening.

3. The temperature-regulating surgical drape of claim toroid describing an annulus about said opening 5, said 60 2 wherein said portion of said opening comprises approximately a 180° portion about said circular opening.

4. The temperature-regulating surgical drape of claim 1 wherein said drape body comprises a first layer and a second layer, and wherein said means for generating heat is disposed between said first and second layers.

5. The temperature-regulating surgical drape of claim 1 wherein said means for generating heat comprises a plurality of chemical reactants adapted to maintain said body portion at said predetermined temperature by reacting with each other upon their admixture.

6. The temperature-regulating surgical drape of claim 1 wherein said drape body includes an upper surface and a lower surface, said lower surface including adhe- 5 sive means located adjacent to said opening for maintaining a body portion other than said predetermined body portion in position below said drape during said surgical procedure.

7. The temperature-regulating surgical drape of claim 10 is disposed between said first and second layers. 6 wherein said adhesive portion comprises a first adhesive portion, wherein said bottom surface of said drape body includes a second adhesive portion for adhesively securing said surgical drape to said body during said

surgical procedure.

8. A temperature-regulating surgical drape for use in conducting surgical procedures on the male scrotum comprising a drape body including an opening adapted to expose only said male scrotum while covering the remainder of said body including the penis during said surgical procedure, and means for generating heat affixed to said drape body at a localized predetermined location surrounding at least a portion of said opening so as to be disposed in contact with said male scrotum during said surgical procedure and thereby selectively maintaining said male scrotum at a predetermined elevated temperature during said surgical procedure.

9. The temperature-regulating surgical drape of claim 8 wherein said opening comprises a circular opening.

10. The temperature-regulating surgical drape of aim 9 wherein enid manufactures claim 9 wherein said means for generating heat is disposed circumferentially around a portion of said circular opening extending approximately 180° about said circular opening.

11. The temperature-regulating surgical drape of claim 8 wherein said drape body comprises a first layer and a second layer, and wherein said means for generating heat is disposed between said first and second layers.

12. The temperature-regulating surgical drape of 40 claim 8 wherein said drape body includes an upper surface and a lower surface, and including adhesive means on said lower surface of said drape body adjacent to said opening so as to maintain said penis in a fixed position during said surgical procedure.

13. The temperature-regulating surgical drape of aim 12 wherein said editorium claim 12 wherein said adhesive means comprises first adhesive means, and including a second adhesive means on said lower surface of said drape for maintaining said surgical drape in position with respect to said body 50 during said surgical procedure.

14. The temperature-regulating surgical drape of claim 8 including activation means for selectively activating said means for generating heat during said surgi-

cal procedure.

15. A temperature-regulating surgical drape for use in conducting surgical procedures on a predetermined body portion of a patient comprising a substantially planar drape body including an opening adapted to expose only said predetermined body portion during 60 said surgical procedure, and means for cooling affixed to said drape body at a localized predetermined location surrounding at least a portion of said opening for maintaining said predetermined body portion at a predetermined reduced temperature during said surgical proce- 65

16. The temperature-regulating surgical drape of claim 22 wherein said opening comprises a circular

6 opening, and wherein said means for cooling surrounds at Jesst a portion of said opening. ...

17. The temperature-regulating surgical drape of claim 23 wherein said portion of said opening comprises approximately a 180° portion about said circular open-

18.4 The temperature-regulating surgical drape of claim 15 wherein said drape body comprises a first layer and a second layer, and wherein said means for cooling

The temperature-regulating surgical drape of claim 15 wherein said means for cooling comprises a plurality of chemical reactants adapted to maintain said body portion at said predetermined reduced tempera-ture by reacting with each other upon their admixture.

20. The temperature-regulating surgical drape of claim 15 wherein said drape body includes an upper surface and a lower surface, said lower surface including adhesive means located adjacent to said opening for maintaining a body portion other than said predetermined body portion in position below said drape during said surgical procedure.

21. The temperature-regulating surgical drape of claim 20 wherein said adhesive portion comprises a first adhesive portion, and wherein said bottom surface of said drape body includes a second adhesive portion for adhesively securing said surgical drape to said body

during said surgical portion.

22. A temperature-regulating surgical drape for use in conducting surgical procedure on the male scrotum comprising a drape body including an opening adapted . to expose only said male scrotum while covering the remainder of said body including the penis during said surgical procedure, and means for cooling affixed to said drape body at a localized predetermined location surrounding at least a portion of said opening so as to be disposed in contact with said male scrotum during said surgical procedure and thereby selectively maintaining said male scrotum at a predetermined reduced temperature during said surgical procedure.

23. The temperature-regulating surgical drape of claim 22 wherein said opening comprises a circular

opening.

24. The temperature-regulating surgical drape of claim 23 wherein said means for cooling is disposed circumferentially around a portion of said circular opening extending approximately 180° about said circular opening.

25. The temperature-regulating surgical drape of claim 22 wherein said drape body comprises a first layer and a second layer, and wherein said means for cooling is disposed between said first and second layers.

26. The temperature-regulating surgical drape of claim 22 wherein said drape body includes an upper surface and a lower surface, and including adhesive means on said lower surface of said drape body adjacent to said opening so as to maintain said penis in a fixed position during said surgical procedure.

27. The temperature-regulating drape of claim 26 wherein said adhesive means comprises first adhesive means, and including a second adhesive means on said lower surface of said drape for maintaining said surgical drape in position with respect to said body during said

surgical procedure.

28. The temperature-regulating surgical drape of claim 22 including activation means for selectively activating said means for cooling during said surgical pro-

### UNITED STATES .

# CERTIFICATE OF CORRECTION

PATENT NO. :

4,807,644

DATED

February 28, 1989

INVENTOR(S):

Jeffrey J. Sandhaus

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 1, line 13, delete "surge ion" and insert therefor --surgeon--.

Column 1, line 24, delete "surge ion" and insert therefor --surgeon--.

Column 5, line 12, following "portion," insert --and--.
Column 6, line 4, delete "23" and substitute therefor --16--.
Column 6, line 30, delete "procedure" and substitute therefor --procedures --.

> Signed and Sealed this Twelfth Day of September, 1989

Attest:

DONALD J. QUIGG

Anesting Officer

Commissioner of Patents and Trademarks



## United States Patent [19]

Ragan et al.

Patent Number:

5,125,238

Date of Patent:

Jun. 30, 1992

[54]	PATIENT BLANKET	WARMING OR COOLING	4,867,230	9/1989	Feher
[75]	Inventors:	Raymond G. Ragan; James G. Stephenson; Charles L. Zuck, all of Marshall, Mich.			Albert J. Makay William C. Doerrler
[73]	Assignee:	Progressive Dynamics, Inc., Marshall, Mich.	(57)		ABSTRACT
[21]	Appl. No.:	692,572			heating or cooling blanket having

[22] Filed: Apr. 29, 1991

Int. Cl.3 

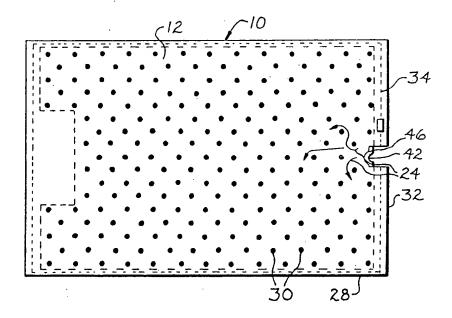
#### [56] References Cited

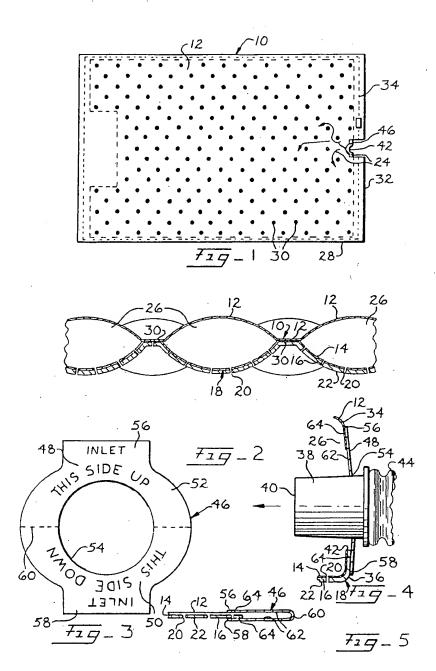
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2.093.834	9/1937	Gaugler	128/145
2.110.022	3/1938	Kliesrath	5/334
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3.942.202	3/1976	Chevrolet	5/348 R
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4.572.188	2/1986	Augustine et al	128/380

A disposable patient heating or cooling blanket having three layers of flexible sheeting two of which form an air chamber, the third of which is a comfortable layer for contact with the patient and which, having a greater friction characteristic, aids in keeping the blanket in place on the patient. The patient is bathed in conditioned air through a multiplicity of orifices in the bottom layers of the blanket and the size and location of the orifices are such that sufficient pressure exists within the blanket to prevent crimping blockage and to insure a uniform flow of air through the orifices throughout the blanket area. Conditioned air is introduced horizontally through an external nozzle which is inserted into a low cost foldable fitting plate bonded to the blanket which permits the blanket to be concisely folded and packaged.

9 Claims, 1 Drawing Sheet





#### PATIENT WARMING OR COOLING BLANKET

#### BACKGROUND OF THE INVENTION

Medical care providers have long recognized the need to provide warmth and cooling directly to patients as part of their treatment and therapy. The relatively recent proliferation of mobile emergency medical facilities as an adjunct to fire departments and the expansion of clinical facility services in the community has increased the number of sites where such treatments must be given. Consequently, there has evolved a need for an inexpensive disposable patient thermal control blanket which will provide a distributed air flow while maintaining sufficient pressure in the blanket to prevent blockage of the flow due to the blanket folding or crimping.

#### FIELD OF THE INVENTION

The present application relates to a patient warming or cooling blanket which employs a bath of temperature controlled air applied to the patient rather than utilizing direct or indirect contact with a heat exchanger.

#### DESCRIPTION OF RELATED ART

Devices of the type described above are well known in the art, for example U.S. Pat. No. 2,093,834 discloses of a mechanism for providing localized air conditioning by means of an inflatable covering constructed of plu- 30 rality of tubular enclosures of porous material in conjunction with a quilted covering. Devices of this construction rely on a recirculating cooling or heating medium and transfer heat mainly through contact with the blanket surfaces. This patented device as well as those of U.S. Pat. Nos. 2,601,189 and 4,572,188 which are also of such essentially tubular or corrugated construction have the disadvantage that they are longitudinally rigid, relatively uncomfortable, have a high profile, and due to the complexity of devices of this type, they are relatively expensive to construct. U.S. Pat. No. 2.093.834 shows a construction which is susceptible to tube wall compression which constricts the flow pathand increases internal pressure resulting in flow restriction and rigidity due to the entrapment of air within the device. The construction of the devices of U.S. Pat. Nos. 2,601,189 and 4,572,188 include lateral passages to adjacent tubes which do not fully alleviate the tube compression flow restriction problem and are more 50 expensive to fabricate than the instant invention by virtue of their complex construction

### OBJECTS OF THE INVENTION

In view of the foregoing shortcomings in pneumatic 55 temperature control patient blanket fabrication, it is an object of the invention to provide a disposable blanket for use in patient warming and cooling applications which is simple to operate, easy to construct, economical to manufacture and concisely storable.

A further object of the invention is to provide a pneumatic blanket which employs materials and structural elements which are comfortable to the patient with whom they contact.

An additional object of the pneumatic patient blanket 65 is to provide an even, pleasant and healthy flow of air uniformly over the covered area regardless of where the blanket air chamber may be compressed.

#### SUMMARY OF THE INVENTION

The invention pertains to disposable heating and cooling patient blankets. An external air conditioning unit provides low pressure heated or dehumidified and cooled air through a flexible hose having a supply nozzle. Conditioned air is introduced into the blanket pneumatic chamber by means of the supply nozzle which inserts into an inlet port through a low-cost folding cardboard fitting plate mounted on the edge of the blanket.

The folding cardboard fitting plate has a folded storage mode to permit the blanket to be folded into a compact mass for storage. In its open operative mode the fitting plate is essentially planar having an opening which is sized to snugly receive the supply nozzle horizontally through the blanket edge directly into a pneumatic flow chamber thereby avoiding opposite wall obstructions of the supply nozzle airflow.

The pneumatic flow chamber is constructed of, and defined by, the interface of two polyethylene sheets heat bonded together at their perimeters and at a plurality of staking points in a single step of the assembly process. Air flow through the blanket is enhanced by the creation of fully redundant flow paths around the staggered dot staking pattern which is distributed throughout the blanket area. A layer of non-woven wood pulp airlaid material is adhesively bonded to the bottom sheet of polypropylene thereby forming a laminated layer and both the bottom sheet of polyethylene and airlaid material are perforated by an array of selectively sized orifices. The orifices are distributed in a regular pattern throughout the area bounded by the pneumatic chamber parameter and allow the emission of an even, gentle air stream from the blanket bottom and are of such size that the blanket will be pressurized enough to hold its shape and resist crimping of the air flow due to normal compressive forces being applied to the blanket. The airlaid material rests comfortably against the patient bathing the patient in the air emitted from the orifices and helps keep the blanket from sliding off the patient because of its high frictional characteris-

#### BRIEF DESCRIPTION OF THE DRAWINGS

In order that the invention may be clearly understood, it will now be described, by way of example, with reference to the accompanying drawings, wherein:

FIG. 1 is a plan view of the patient blanket in accord with the invention,

FIG. 2 is an enlarged, cross-sectional, detail elevation view of the blanket showing the pneumatic chamber between staking points as well as the relationship of the several blanket layers in accord with the invention,

FIG. 3 is an elevational view of the folding cardboard fitting plate in accord with the invention shown in the open or unfolded mode,

FIG. 4 is an enlarged, elevational, detail sectional view of the folding cardboard fitting plate air inlet connection with an external air supply nozzle inserted therein in accord with the invention, and

FIG. 5 is an enlarged, elevational, detail view of the cardboard fitting plate as attached to the blanket in accord with the invention and shown in the folded storage condition.

## DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the invention, a three layer construction is employed to form the patient blanket 10 with two layers forming an air chamber and a third layer providing a comfortable surface for contact with the patient. It will be obvious to a person familiar in the art, that any of a number of flexible sheeting materials can be used for the upper flexible sheet 12 and lower flexible sheet 14, but in 10 the preferred embodiment for economy, strength and flexibility considerations 1.5 mil thickness polyethylene sheeting was selected. Simple, economical assembly of the blanket begins when the .015 inch thick layer of non-woven fibrous layer of wood pulp airlaid material 16 is adhesively bonded to the lower side of the 1.5 mil thickness lower flexible sheet 14 forming the laminate assembly 18, as shown in FIG. 2. This fibrous layer 16 provides a comfortable surface in contact with the patient and its high frictional characteristic helps keep the blanket in place on the patient. A material of this type is available under the trademark "AIRTEX" from the Fiberware Corporation. The laminate assembly 18 is then perforated with specifically sized orifice holes 20 by means of a punch plate. The orifice size is deter- 25 mined by the volume flow characteristics of the air source and by the following formula:

 $Q = KA \sqrt{\Delta P}$ 

Where Q is the air flow rate in cubic feet per minute. K is a constant, A is the area of the orifices and ΔP is the differential pressure in inches of water at standard room conditions. From test results it was determined that for proper flow and inflation K should be 11.718, A should equal 0.001 square inches for each square inch of blanket which will produce 0.035 inch diameter orifices on 1 inch centers and ΔP is 0.25 inches of water.

The sizing of the orifices 20 by this method assures sufficient inflation to minimize crimping of the blanket while providing continuous air flow to the lower surface 22 that is both evenly distributed and above the minimum flow quantity required. The problems associated with compressing or crimping the blanket are also alleviated through the invention's incorporation of a multiplicity of redundant flow paths as shown by the arrows 24 within the pneumatic flow chambers 26 as shown in FIG. 1 due to the inflation of the blanket.

Subsequent to the lower layer lamination and orifice perforation, the upper flexible sheet 12 is laid upon the laminated assembly 18 and the periphery 28 of the two 50 polyethylene layers are heat sealed together. In the same process step, the two flexible sheets are also staked together in a staggered pattern of one inch diameter heat sealed staking bonds or welds 30 throughout the area within the periphery seal. This staking creates the 55 redundant flow paths 24 feature of the invention as well as serving the dual purposes of reducing stresses to the inflated structure through reducing the radius of the chambers 26, and through the same mechanism reducing the blanket inflated thickness while assuring flow 60 distribution and continuity across the lower surface 22 of the blanket.

The preferred air inlet location is through a fitting plate on the blanket edge 32 intermediate the upper flexible sheet first end 34 and the lower flexible sheet 65 first end 36. In this blanket edge center, a semicircular cut is made through the laminated assembly 18 and the upper flexible sheet 12. When the blanket is inflated,

these semicircular cuts form an essentially horizontal circular air inlet port 42. By horizontal insertion of an air supply nozzle through the fitting plate into the blanket air flow is unrestricted by blanket film members pressing against the nozzle opening, and furthermore, there is no need to support the nozzle's weight. The conditioned air is introduced through a flexible hose 44 having a frustoconical end nozzle 38 converging towards the nozzle end 40.

The fitting plate 46, in accord with the invention, is best shown in FIGS. 3, 4 and 5. The plate 46 is fabricated of a low cost, foldable material with an exterior surface suitable for direct labeling. In the preferred embodiment, cardboard was selected as meeting the aforementioned criteria as well as being an inexpensive and easy to print material. The fitting plate 46 is an elongated member having a first end 48 and a second end 50 each with an extension and having a circular central portion 52 intermediate the ends. The circular center portion 52 defines an opening 54 which aligns with the blanket chamber port 42 to snugly receive the frustoconical air supply nozzle 38, thereby introducing conditioned air into the pneumatic flow chambers 26 when the fitting plate 46 is opened to its unfolded planar operative configuration as best seen in FIGS. 3 and 4. This open configuration provides full open area flow into the pneumatic flow chambers 26 through the port 42 and provides for easy nozzle 38 insertion into the blanket 10 edge 32.

As seen in FIG. 3, the fitting plate 46 preferably contains explanatory labeling to assist the user in the proper use of the invention and provides for simultaneous labeling of the blanket upper and bottom surfaces without additional labels. The plate first end extension 56 and second end extension 58 are labeled with the words "INLET" to mark the port 42 location into which the conditioned supply air is introduced. On the circular center portion 52, the plate first end 48 to which the upper sheet 12 is attached is identified by the words "THIS SIDE UP", and the plate second end 50 to which the blanket lower surface 22 is attached is identified by the words "THIS SIDE DOWN". Intermediate the plate first end 48 and second end 50 on the center portion \$2 is a fold line 60 identified by dashed lines across the fitting plate central portion 52. This fold line is aligned with the blanket edge 32 when the fitting plate 46 is installed on the blanket 10.

Semicircular cuts are made in the blanket upper sheet and lower sheet first ends 34 as seen in FIG. 1, which define the blanket chamber port 42 at which the fitting plate 46 is mounted as in FIG. 1. The plate 46 is aligned with the upper sheet 12 and the laminated assembly 18 and installed in line with the blanket edge 32 forming a hinge-like relationship with the blanket edge 32 as seen in FIG. 5. Because the adhesive is applied only to the plate center portion 52 inner side 62, forming a bond 64, the end extensions are free of the blanket surfaces. By remaining free, the inflated blanket profile and stress to the adhesive bond 64 during inflation are minimized; and the plate first end extension 56 and the plate second end extension 58 may be grasped and separated during nozzle insertion. As shown in FIG. 5, the fitting plate 46 provides concise packaging because it compactly folds along the plate fold line 60 providing a low profile; this configuration has the further advantage of reducing the stress to the interface bond 64 during storage and packThe external conditioned air supply, not shown, can be a separate heating or cooling/dehumidification unit or a unified system and forms no part of the invention. The air supplies are typically transportable low pressure units, similar to a hair dryer construction or the like, having a moderate volume flow rate for which the orifices 20 are sized. The air supply is connected to the blanket by means of the flexible hose 44 as described below.

The pneumatic blanket 10 is typically used to adjust 10 or maintain patient body temperatures through the application of either warming or cooling air for surgical, post operative, hypothermic or hyperthermic patients. In use, pneumatic blanket 10 is fully opened and positioned to cover the body area to be treated; if the whole body is to be covered, then the blanket is positioned lengthwise over the patient with the fitting plate 46 adjacent the patient's feet. Next, the fitting plate 46, which has been folded during storage, is grasped with appropriate fingers behind the extensions 56 and 58 and 20 the thumb or thumbs are positioned at the plate fold line 60 on the outer surface of the plate. By pressing inwardly on the plate fold line 60 while separating extensions 56 and 58 the fitting plate may be opened to a substantially vertical planar configuration as shown in 25 FIG. 4. Next, while maintaining pressure on the fitting plate 46 such that it is in the open, planar configuration the air supply nozzle 38 is inserted into the fitting plate central opening 54 until a snug sealed fit between the plate 46 and the nozzle 38 is obtained as in FIG. 4. Of course, the size of the nozzle 38 and opening 54 are such that the nozzle will tightly wedge into the opening 54 to form an effective seal. Conditioned air may now be supplied to the nozzle which will inflate the blanket and cause the air within the blanket 10 to be exhausted 35 through the blanket orifices 20 in the blanket bottom. By bathing the patient in a constant, gentle flow of air the desired body temperature effect may be achieved without the tissue damage or discomfort often caused by indirect or direct contact with a heat exchanging 40 member.

It is appreciated that various modifications to the inventive concepts may be apparent to those skilled in the art without departing from the spirit and scope of the invention.

1. A pneumatic, disposable, temperature control blanket receiving conditioned air though an external air supply connection means, comprising, in combination. an upper thermoplastic air impervious flexible sheet and 50 a lower thermoplastic flexible sheet each having a first end, an opposing second end and edges defining a periphery, said first end lower flexible sheet being adjacent said first end upper flexible sheet, said lower sheet having a lower bottom surface, a heat seal bonding said 55 upper flexible sheet periphery to said lower flexible sheet periphery, a pneumatic flow chamber defined by said sheets, said upper flexible sheet being heat sealed to said lower flexible sheet at a multitude of staking points distributed in a staggered pattern within said sheets' peripheral edges thereby defining redundant multiple air flow paths within said pneumatic flow chamber, an inlet air port defined in said pneumatic flow chamber, an inlet air connection means affixed to said sheets in communication with said inlet air port adapted to re- 65 ceive the inlet air supply connection means to inflate said pneumatic flow chamber, an outer fibrous bottom lamina material bonded to said lower flexible sheet

bottom surface thereby comprising a lower laminated assembly to provide a slide resistant comfortable patient contact surface, an outwardly disposed air flow orifice array defined in said laminated assembly in communication with said pneumatic flow chamber to convey temperature controlled air from said pneumatic flow chamber to the patient, said orifice array comprising a plurality of substantially evenly spaced openings defined in said laminated assembly sized to maintain a predetermined pneumatic flow chamber pressure over a range of predetermined air source volume flow rates.

2. A pneumatic, disposable, temperature control blanket as in claim 1, wherein said inlet air connection means comprises a folding plate affixed to said sheets adjacent said edges thereof defining an opening in communication with said inlet air port adapted to receive the air supply connection means.

3. A pneumatic, disposable, temperature control blanket receiving conditioned air through an external air supply connection means, comprising, in combination, an upper flexible sheet and a lower flexible sheet each having a first end, an opposing second end and edges defining a periphery, said first end lower flexible sheet being adjacent said first end upper flexible sheet, a peripheral bonding means bonding said upper flexible sheet periphery to said lower flexible sheet periphery, a pneumatic flow chamber defined by said sheets having walls, an inlet air port defined in said pneumatic flow chamber, an inlet air connection means affixed to said sheets in communication with said inlet air port adapted to receive the inlet air supply connection means to in-flate said pneumatic flow chamber, an outer fibrous bottom lamina material bonded to said lower flexible sheet thereby comprising a laminated assembly to provide a slide resistant comfortable patient contact surface, an outwardly disposed air flow orifice array defined in said laminated assembly in communication with said pneumatic flow chamber to convey temperature controlled air from said pneumatic flow chamber to the patient, said orifice array comprising a plurality of openings sized to maintain pneumatic flow chamber pressure over a range of air source volume flow rates, said inlet connection means comprising an articulating fitting plate having a folded mode and an unfolded inflation mode, an opening defined in said fitting plate in communication with said port adapted to sealingly receive the air supply connection means when said plate is in said unfolded mode, said fitting plate being attached said upper flexible sheet first end and said lower flexible sheet first end, said inlet air port and fitting plate being located intermediate said upper and lower flexible sheets at said sheet's edges to permit the introduction of supply air in said chamber in the direction of the general plane of the blanket minimizing flow restrictions

4. A pneumatic, disposable, temperature control blanket for receiving conditioned air through an external air supply nozzle, comprising, in combination, a substantially planar chamber having a flexible upper wall, a flexible lower wall and an edge, a port communicating with said chamber defined in said edge, a folding fitting plate affixed to said upper and lower walls having a central opening in communication with said port, said fitting plate having a fold line in alignment with said chamber edge, said fitting plate central opening adapted to slidingly, sealingly receive the air supply nozzle in the blanket plane upon said plate being unfolded, an orifice array defined in said lower chamber wall, said crifices being in communication with said chamber

7 outwardly disposed to discharge chamber air onto the

patient.

5. A pneumatic, disposable, temperature control blanket as in claim 4, wherein said fitting plate comprises an elongated member having a first end defining a first end 5 extension, a second end defining a second end extension and a circular portion intermediate said first and second ends, said circular portion having a central opening defined therein in alignment with said port, adapted to receive the air supply nozzle.

6. A pneumatic, disposable, temperature control blan-ket as in claim 5, wherein said fitting plate circular portion only is sealingly bonded to said flexible upper wall and said flexible lower wall at said blanket edge thereby leaving said plate extensions free to move relative said blanket, said circular portion central opening

adapted to align and communicate with said port.

7. A pneumatic, disposable, temperature control blanket as in claim 5, wherein said fitting plate is fabricated of a flexible, foldable material with an outer surface adapted to receive indicia thereon.

8. A pneumatic, disposable, temperature control blanket as in claim 7, indicia located on said fitting plate

 outer surface for explanatory and orientation purposes.
 A pneumatic, disposable, temperature control blanket as in claim 7, wherein said fitting plate material is cardboard.

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### United States Patent [19]

Augustine et al.

[11] Patent Number:

5,324,320

Date of Patent: \* Jun. 28, 1994

#### [54] THERMAL BLANKET

[75] Inventors: Scott D. Augustine; Douglas J. Augustine, both of Blue Springs, Mo.

Augustine Medical, Inc., Eden [73] Assignee:

Prairie, Minn.

The portion of the term of this patent [\*] Notice: subsequent to Feb. 9, 2010 has been

disclaimed.

[21] Appl. No.: 703,592

[22] Filed: May 20, 1991

#### Related U.S. Application Data

Continuation of Ser. No. 227,189, Aug. 2, 1988, abandoned, which is a continuation-in-part of Ser. No. 104,682, Oct. 5, 1987, abandoned.

[51]	Int. Cl.5	A61F 7/00
		607/107; 165/46;
		5/487

[58] Field of Search ..... 62/259.3; 165/46; 5/482, 485

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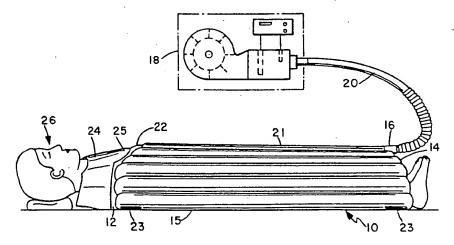
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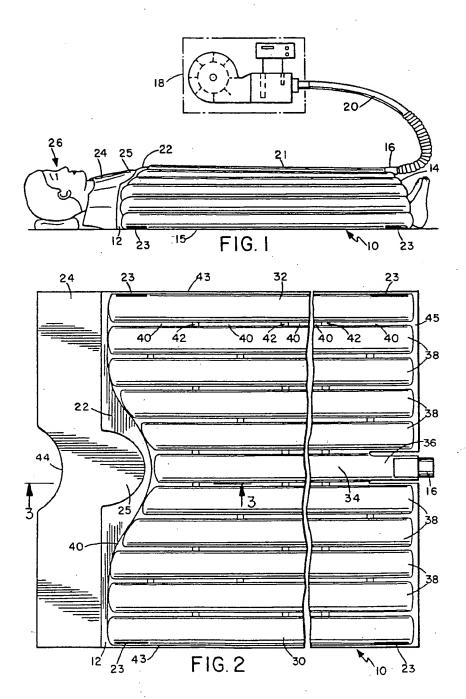
Primary Examiner-Mark S. Graham Attorney, Agent, or Firm-Baker, Maxham, Jester & Meador

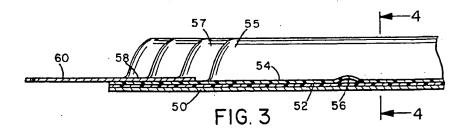
#### ABSTRACT

A thermal blanket includes an inflatable covering with a head end, a foot end, two edges and an undersurface. The covering is inflated through an inlet at the foot end by a thermally-controlled inflating medium. An aperture array on the undersurface of the covering exhausts the thermally-controlled inflating medium from the covering. Exhaust port openings are provided at the edges of the covering to vent the inflating medium, which enhances circulation of the thermally-controlled medium through the cover. An uninflatable section is provided at the head end, together with an absorbent bib attached to the covering, adjacent the uninflatable section. When inflated, the thermal blanket self-erects and provides a bath of thermally-controlled inflating medium to the interior of the erected structure. The enhanced circulation of the medium through the covers maintains a relatively high average temperature under the blanket and a relatively uniform distribution of temperature in the inflating medium which is exhausted through the apertures into the structure's interior. When the structure covers a patient, the uninflatable section provides a relatively unobstructed view of the patient's face, while the absorbent bib maintains a relatively sanitary environment in the area beneath the patient's head.

#### 24 Claims, 2 Drawing Sheets







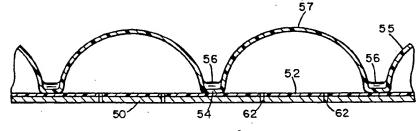


FIG. 4

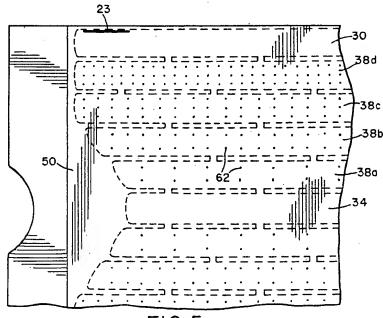


FIG. 5

### THERMAL BLANKET

This is a continuation (FILE WRAPPER) of application Ser. No. 07/227,189 filed Aug. 2, 1988, abandoned, which is a continuation-in-part of application Ser. No. 07/104,682 filed Oct. 5, 1987, abandoned.

#### BACKGROUND OF THE INVENTION

This invention relates to thermal blankets used in a 10 medical setting to deliver a bath of a thermally-controlled medium to a patient.

The thermal blanket prior art is best expressed in our prior U.S. Pat. No. 4,572,188 entitled "AIRFLOW COVER FOR CONTROLLING BODY TEMPERA. 15 TURE." In our prior patent, a self-erecting, inflatable airflow cover is inflated by the introduction into the cover of a thermally-controlled inflating medium, such as warmed air. When inflated, the cover self-erects about a patient, thereby creating an ambient environment about the patient, the thermal characteristics of which are determined by the temperature of the inflating medium. Holes on the underside of our prior art airflow cover exhaust the thermally-controlled, inflating medium from inside the cover to the interior of the erected structure. Our airflow cover is intended for the treatment of hypothermia, as might occur postoperatively.

Evaluation of our airflow cover by skilled practitioners has resulted in general approbation: the opinion is that the airflow cover efficiently and effectively accomplishes its purpose of giving a thermally-controlled bath. We have realized, however, that, while our prior art airflow cover achieves its objective, certain improvements to it are necessary in order to realize additional clinical objectives and to enjoy further advantages in its use.

#### SUMMARY OF THE INVENTION

We have improved the clinical usefulness of our selferecting airflow cover by observing that controlling the contour of its inflatable portion at its head end to define a generally concave non-inflatable portion will permit a care giver to more easily observe a patient's head, face, neck and chest. Further, we have observed that limited venting of the thermally controlled inflating medium from the edges of the cover results in more efficient, more uniform heating within the cover. We have also observed that it is good clinical practice to keep the area of the care site in the vicinity of the patient's head and face as clean as possible.

These three observations have resulted in an improved thermal blanket in which a self-erecting inflatable covering has a head end, a foot end, two edges, and 55 an undersurface. An inflating inlet adjacent said foot end admits a thermally-controlled inflating medium into the covering. An aperture array on the undersurface of the covering exhausts the thermally-controlled inflating medium from the covering into the structure created 60 when the covering self-erects upon inflation. The improvements to this basic structural complement include an uninflatable section at the head end of the covering, exhaust port openings at the edges of the covering, an absorbent bib attached to the covering at the head end 65 adjacent the uninflatable section, and structural features that make the covering simple and economical to produce.

With these improvements, the thermal blanket, when inflated and erected over a patient, delivers the thermally-controlled inflating medium into the interior of the structure covering the patient, thereby thermally bathing the patient. The first improvement permits full viewing of the head and face of the patient from almost any aspect around the thermal blanket. The exhaust port openings increase the rate of circulation of the inflating medium within the blanket, thereby increasing

the temperature within the structure and making the temperature distribution more uniform. The absorbent bib soaks up and retains liquids which might otherwise spread over the care site in the area of a patient's head. Such liquids can include the patient's own perspiration, blood, vomit, saliva, or liquids which are administered to the patient. The absorbent bib also acts to some extent to seal the head end of the inflated structure.

From another aspect, the invention is a thermal blanket for covering and bathing a person in a thermallycontrolled medium. The thermal blanket includes a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures opening between the first and second surface of the base sheet. An overlying material sheet is attached to the first surface of the base sheet by a plurality of discontinuous seams which form the material sheet into a plurality of substantially parallel, inflatable chambers. A continuous seam is provided between the material sheet and the base sheet at the head end to form a non-inflatable viewing recess at the head end. Exhaust port openings are provided through the material sheet to vent the medium from the chambers away from the base sheet. An absorbent bib is attached to the head end in the vicinity of the viewing recess.

Therefore the invention accomplishes the important objective of providing a self-erecting, inflatable thermal blanket that permits a relatively unobstructed view of a patient's head and face when in use.

Another objective is the efficient and uniform heating of the interior of the structure created when the blanket is inflated with a heat inflating medium.

A signal advantage of the invention is the provision of such a blanket with a means for maintaining the cleanliness of the care site in the vicinity of the patient's head and face.

The advantageous simplified structure of the thermal blanket make its production straightforward and economical.

These and other important objectives and advantages will become evident when the detailed description of the invention is read with reference to the below-summarized drawings, in which:

FIG. 1 is a side elevation view of the thermal blanket in use, with associated thermal apparatus indicated schematically;

FIG. 2 is an enlarged top plan view of the thermal blanket opened flat;

FIG. 3 is an enlarged sectional view taken along 3-3 of FIG. 2;

FIG. 4 is a further enlarged sectional view taken along line 4—4 of FIG. 3; and

FIG. 5 is a partial underside view of the thermal

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

When used herein, the term "thermal blanket" is intended to be interchangeable with, but not necessarily

limited by, the term "airflow cover" used in our U.S. Pat. No. 4,572,188, which is incorporated herein in its entirety by reference. In this description, the term "thermal blanket" is meant to invoke a self-erecting, inflatable structure for delivering a thermally-controlled inflating medium to the interior of the structure created when the thermal blanket is inflated. The purpose of the thermal blanket is to efficiently administer a uniformly thermally-controlled bath of the inflating medium to a patient within the erected structure.

Our invention is illustrated as we intend for it to be used in FIG. 1. In FIG. 1, a self-erecting, inflatable thermal blanket 10 has a head end 12, a foot end 14 and two lateral edges, one indicated by 15. An inflation inlet cuff 16 is connected to a heater/blower assembly 18 15 which provides a stream of heated air through a connecting hose 20. When the heater/blower 18 is operated, the stream of heated air flows through the inflating hose 20 into the thermal blanket 10 through the inflation cuff 16. When the blanket is inflated, it erects itself into 20 a Quonset hut-like structure with a quilted upper surface 21. As described below, a pattern of apertures on the undersurface of the blanket (not shown in FIG. 1) delivers the inflating heated air into the interior space enclosed by the erected thermal blanket.

The contour of the inflatable portion of the thermal blanket 10 is varied at the head end 12 of the blanket to provide a non-inflated blanket recess 22 in the quilted upper surface 21, which remains smooth and flat when the blanket is inflated and erected. Circulation of the 30 heated air is accelerated through the thermal blanket by exhaust port openings in the upper surface, adjacent the lateral edges of the blanket. Two exhaust port openings are indicated by reference numeral 23. Further, a bib 24 made of an absorbent material is attached to the head 3 end 12 of the thermal blanket in the vicinity of the non-inflated recess 22. In fact, as shown in FIG. 1 the bib 24 includes a semi-circular tab 25 that extends into the

As illustrated in FIG. 1, the thermal blanket of the 40 invention is inflated, erects itself into a bathing structure, and bathes a patient 26 with the thermally-controlled air used to inflate the structure. While the patient is being thermally bathed, the uninflated recess 22 permits observation of the patient's head, face, neck, and 45 chest from almost any location with respect to the thermal blanket 10. Thus, if the patient is placed on a gurney or a bed, the head of which is against a wall, a care giver such as a nurse, intern, resident, or doctor, can keep the patient's face under observation from the foot end 14 of 50 the thermal blanket 10. Respiration can be detected by the rise and fall of the bib and uninflated area, which rest directly on the patient's chest. Moreover, the bib 24 will provide an absorbent sink for stray, unconfined liquids in the area of the patient's head or at the head 55 end 12 of the thermal blanket 10.

FIG. 2 is a plan view of the thermal blanket 10 opened flat to show details of its structure. FIG. 2 illustrates the upper surface of the thermal blanket, that is the side that is visible in FIG. 1. As seen, the upper 60 surface consists of a parallel array of elongated tubes of which 30 and 32 are the lateralmost tubes, 34 is the center tube, and the tubes 38 are arrayed between one of the lateralmost tubes and the center tube. Each tube is separated from an adjacent tube by a discontinuous 65 seam, one of which is indicated by 40. The seam 40 separates the tube 32 and its nearest adjacent neighbor 38. The discontinuous seam 40 is interrupted by pas-

sageways 42 communicating between the tubes. An interrupted seam separates every tube from one adjacent neighboring tube. The seams permit the thermal blanket, when inflated, to assume a tubular structure on the upper surface, while the ports 42 permit full circulation of the inflating medium throughout the array of tubes. The foot-end seam 45 is continuous. The tubes are inflated through the center tube 34 which transitions to a port 36, through which the inflation cuff 16 is in-10 serted. The edge seams 43 are discontinuous only at the exhaust port opening locations 23. A seal can be made between the inflation port 36 and the inflation cuff 16 by any conventional means, for example, an 0-ring, or even tape. When the inflating medium is introduced into the center tube 34, it flows laterally from the center tube into all of the other tubes through the ports 42. Near the head end 12, a continuous seam 40 defines the forward end of all of the tubes, with the seam assuming a bellcurve shape. On the head end side of the seam 40, the thermal blanket 10 is uninflatable. The bell-shaped seam 40 thus defines the uninflatable area 22 at the head end of the thermal blanket 10, which is essentially coplanar with, or substantially parallel to, the underside of the blanket. As shown in FIG. 1, by virtue of its structural integration with the rest of the thermal blanket 10, the non-inflated recess extends over the upper chest of the patient 26 when the blanket is inflated. However, since the recess 22 is uninflated, it provides a wide-angled viewing gap in the inflated contour of the upper surface 21. The gap is filled by continuation of the underside of the blanket. It is also noted that the pattern of inflatable tubes can be replaced by other suitable patterns of communicating, inflatable chambers. The tubes are preferred since they impart strength and shape to the

The absorbent bib has an indent 43 cut into its outside edge, which permits the blanket to be drawn up to the chin of a patient and which provides absorbency laterally up the neck of the patient. The absorbent bib can consist of any absorbent material such as a single or multi-ply tissue paper which is used to make paper towels.

erected bathing structure; other inflatable structures are

contemplated, however.

Construction details of the thermal blanket 10 are illustrated in FIGS. 3 and 4. The thermal blanket 10 is assembled from a base sheet consisting of an underside layer 50 formed from flexible material capable of bonding to a layer 52 of heat-sealable plastic. For the layers 50 and 52, we have used a stratum of absorbent tissue paper prelaminated with a layer of heat-sealable plastic. Material of such construction is commercially available production rolls and is used to make painters' drop cloths. The upper side of the thermal blanket consists of a sheet of plastic bonded to the plastic layer 52 by an interruptible heat-sealing process to form the interrupted seams, one of which is indicated by 54, and the inflatable tubes, one indicated by 55. As can be seen in FIG. 3, the interruption of the seam 54 forms a passageway 56 between adjacent tubes 55 and 57.

The absorbent bib and tab are shown in FIG. 3 as a single material layer 60/58. Alternatively, they may be formed from separate material sheets cut to the outlines illustrated in FIG. 2. The absorbent material forming the bib and tab can be bonded to the upper plastic layer by heat process or by gluing.

The inventors also contemplate deletion of the bib and tab. In this instance, the thermal blanket would still have the viewing recess, which would be defined by the

continuous seam at the head end, and which would be filled with the forward portion of the base sheet. Circulation of heated air through the blanket is en-

hanced by the exhaust port openings 23, which open through the upper plastic sheet sheet, which is heat 5 sealed to the base of the blanket. The openings 23 vent the heated inflating air out of the outermost tubes 30 and 32, away from the underside of the blanket. Because air can circulate to, and through, the blanket edges, the inflating air in the outermost tubes is hotter than if the 10 openings were absent. This results in hotter air being delivered through the underside apertures toward the edge of the blanket. We have measured the temperature distribution within the thermal blanket for inflating air which is heated to a medium temperature range and for 15 inflating air which is heated to a high temperature range. The results are provided in Table I for a blanket consisting of 13 tubes. Measurements of the temperature of air exhausted through underside apertures were made on the underside of each tube on one side of the 20 blanket. The tubes are numbered 1-6, with 1 being the tube adjacent to the center tube, and tube 6 being the outermost tube adjacent on lateral edge of the blanket. Test apertures were made in the bottom of tube 6 only for the purposes of this test. As is evident, the distribution of temperature within the erected thermal blanket is more uniform when the exhaust port openings are provided. Further, provision of the exhaust ports also increases the average temperature within the erected structure of the blanket. Clearly, the provision of exhaust port openings at the lateral edges of the blanket delivers results which one would not expect when considering the operation of our thermal blanket with no exhaust port openings.

In our preferred embodiment, the exhaust port openings are slits in the edge seams of our blanket. These slits vary in length from 1\(\frac{1}{2}\) to 2 inches. Each edge seam is discontinuous approximately at each corner of the blanket so that inflating air is vented away from the underside of the erected blanket. This keeps the relatively "colder" air at the blanket edges from mixing with the relatively "hotter" air exhausted into the structure through the underside apertures. The result is a "flatter" temperature profile of air within the blanket than without the vents, which raises the average temperature distribution in the structure and makes the temperature distribution in the structure more uniform. Resultantly, the clinical effect of the blanket is enhanced. Heating is better controlled, and more uniform, with greater comfort to the patient.

TABLE I

	MEDIUM TEMPERATURE RANGE		HIGH TEMPERATURE		- 55
TUBE NO.	WITHOUT EXHAUST PORTS	WITH 2" EXHAUST PORTS	WITHOUT EXHAUST PORTS	WITH 2" EXHAUST PORTS	- ,
center (inlet) tube	113.3° F.	114.1° F.	121.3° F.	121.3° F.	6
Tube #1	109.9*	112.3"	117.3*	117.7"	
Tube #2	105.3"	109.8"	113.4"	115.0*	
Tube #3	103.2*	107.1"	111.0*	113.3*	
Tube #4	99.9*	104.3*	101.4*	103.6"	
Tube #5	97.2*	100 0	95.7"	104.4*	6
Tube #6 (outer- most)	85.2*	95.8*	, 89.6°	99.4*	Ĭ
Average	103.8*	106.7*	108.4*	112.5*	

TABLE I-continued

	TEMPE	NUM RATURE NGE	HIGH TEMPERATURE RANGE	
TUBE NO.	WITHOUT EXHAUST PORTS	WITH 1" EXHAUST PORTS	WITHOUT EXHAUST PORTS	WITH 2" EXHAUST PORTS
temp. under cover				

The thermal blanket of the invention is enabled to bathe a patient in the thermally-controlled inflating medium introduced into the upper side tubes by means of a plurality of apertures, 62 shown in FIGS. 4 and 5. The apertures extend through the underside of the blanket, which includes the layers 50 and 52. The apertures 62 are made in the footprints of the tubes of the blanket upper side according to a pattern which has been determined to deliver a very uniform thermal bath. In this regard, no apertures are provided through the underside into the lateralmost tubes 30 and 32, or into the center tube 34. In addition, the apertures 62 are provided through the underside to the apertured tubes in a density which varies inversely with the proximity of the tube to the center tube 34. Thus, the hole density increases from the tube 38a through the tube 38d. Even with the exhaust port openings, the temperature of the inflating medium exhibits a drop from the center to the lateralmost tubes. The varying density of the apertures 62 tends to reduce this gradient further by forcing hotter air to the edges of the blanket. Thus, the thermal bath delivered to the patient is of a generally uniform temperature. The aperture density variation also equalizes the flow of inflating medium out of the apertures. As will be evident, the inflating pressure will be greatest at the center tube 34 and will tend to diminish toward the lateral edges of the thermal blanket. Therefore, fewer apertures are required for the tubes near the center tube 34 to deliver the same amount of air as the relatively greater number of apertures in the tubes at a greater distance from the center tube 34.

The apertures comprise openings which can be of any appropriate shape. For example, we have produced blankets with elongated apertures, approximately ‡ inch in length

Many modifications and variations of our invention will be evident to those skilled in the art. It is understood that such variations may deviate from specific teachings of this description without departing from the essence of the invention, which is expressed in the following claims.

We claim:

 In a self-erecting, inflatable thermal blanket for covering and bathing a person in a thermally-controlled medium, the improvement comprising:

a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;

- an overlaying plastic sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said plastic sheet into a plurality of communicating inflatable chambers, said apertures opening through said base sheet into said chambers;
- a continuous seam between said plastic sheet and said base sheet at said head end which forms a non-inflatable viewing recess; and

an exhaust vent in said overlaying plastic sheet and adjacent a first edge, opening from a first inflatable chamber adjacent said first edge, for venting an inflating medium away from said base sheet.

2. The self erecting, inflatable thermal blanket of 5 claim 1 including an absorbent bid attached to the head

end of said base sheet.

3. In a self-erecting, inflatable, convective thermal blanket for covering and bathing a person with a thermally-controlled, inflating medium wherein the im- 10 provement comprises:

a flexible base sheet having two ends and two edges; a flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form a plurality of communicating, 15 inflatable chambers between said flexible base sheet and said flexible material sheet;

a means for admitting an inflating medium into said chambers:

said flexible base sheet including means for permitting 20 passage of said inflating medium from said chambers through said flexible bas sheet; and

vent means in said flexible material sheet adjacent a first edge of said flexible base sheet for circulating said inflating medium through said inflatable cham- 25 bers by exhausting said inflating medium from a first inflatable chamber adjacent said first edge

4. The thermal blanket of claim 3, wherein said flexible base sheet includes an undersheet of flexible fibrous material and a sheet of plastic material coextensive 30 with, and attached to, said undersheet.

5. The thermal blanket of claim 4, wherein said discontinuous seams are substantially elongate seals, formed between said flexible material sheet and said flexible base sheet, which form said inflatable chambers 35 into a plurality of mutually parallel, communicating tubular chambers extending between said two ends.

6. An inflatable, convective thermal blanket for cov ering and bathing a person in a thermally-controlled inflating medium, comprising:

a flexible base sheet having ahead end, a foot end, two edges, and a plurality of apertures;

an plastic sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said plastic sheet into a plurality of communi- 45 cating, inflatable chambers, said apertures opening through base sheet into said chambers; and

an exhaust vent opening through said plastic sheet into a first inflatable chamber adjacent said first edge, for circulating an inflating medium through 50 said inflatable chambers by venting said inflating medium from said first inflatable chamber

7. In a self-erecting, inflatable thermal blanket for covering and bathing a person in a thermally-controlled inflating medium, the improvement comprising:

a flexible base sheet having a head end, a foot end,

two edges, a plurality of apertures;

an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying 60 material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers.

a continuous seam between said overlaying material sheet and said base sheet near said head end which 65 closed ends of said inflatable chambers; and

a non-inflatable section of said thermal blanket extending substantially between said continuous seam

and said head end and including an end portion of said flexible base sheet.

8. The improvement of claim 7 wherein said base sheet includes an undersheet of flexible fibrous material and a sheet of plastic material co-extensive with, and attached to, said undersheet.

9. The improvement of claim 7 wherein said base sheet includes a multi-layered structure in which the bottom-most layer is a paper sheet bonded to an upper

sheet of plastic material.

10. The improvement of claim 8 wherein said discontinuous seams are substantially elongate seals formed between said overlaying material sheet and said sheet of plastic material, and said continuous seam is an elongate seal which extend between said edges substantially transversely to said elongate seals.

11. The improvement of claim 8 wherein one of said discontinuous seams includes a sequence of co-linear seals extending substantially from said foot end to said

continuous seam.

12. The improvement of claim 11 wherein said plurality of discontinuous seams form said overlaying material sheet into a plurality of mutually parallel, communicating tubular chambers.

13. The improvement of claim 7 including exhaust port openings through aid overlaying material sheet for circulating said inflating medium within said thermal blanket toward said two edges.

14. The improvement of claim 7 including a patterned array of apertures opening through said underside into said chambers, said patterned array comprising a density pattern in which the density of said apertures increases toward one of said edges.

15. The improvement of claim 12 including a patterned array of apertures, said apertures opening through said base sheet into said chambers, said patterned array comprising a density pattern in which the density of said apertures increases toward one of said

40 edges.

16. The improvement of claim 15 wherein one of said tubular chambers is centrally positioned in said parallel tubular chambers and said density increases from said central position chamber toward one of said edges.

17. The improvement of claim 16 wherein no apertures open through said base sheet into said centrally positioned tubular chamber.

18. The improvement of claim 17 wherein no apertures open through said base sheet into a tubular chamber adjacent one of said edges.

19. An inflatable thermal blanket for convectively controlling the temperature of a human body, compris-

a self-erecting, inflatable covering with a head end, a foot end, two edges, and an undersurface

an inflating inlet for admitting a thermally controlled, inflating medium into said covering;

an array of apertures in said undersurface for exhausting a thermally controlled inflating medium from said covering to said undersurface;

means in said inflatable covering for equalizing the temperature of the thermally controlled inflating medium in said inflatable covering by circulating said inflating medium toward said two edges; and an inflatable extension in said inflatable covering at

wherein said array of apertures is in a pattern which increases the density of said apertures from a central location on said undersurface in a direction toward a first one of said two edges.

20. The thermal blanket to claim 19 wherein the pattern increases the density of said apertures from said central location in a direction toward the second of said two edges.

21. A convective thermal blanket for being inflatably erected to enclose and bathe a person in a thermallycontrolled inflating medium, comprising:

flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures, the base sheet including a first layer of non-plastic material and a second layer of plastic material attached to said 15 first layer:

an overlaying plastic sheet attached to said second layer of said base sheet by a plurality of discontinuous means which form said plastic sheet into a plurality of communicating, inflatable chambers, 20 said apertures opening through said base sheet into said chambers:

a continuous seal transverse to and closing ends of said inflatable chambers, the continuous seal being 25 between said plastic sheet and said second layer of said base sheet near said head end; and

an uninflatable viewing portion extending between said head end and said continuous seal, said viewing portion including respective extensions of said 30 base sheet and said plastic sheet.

22. A self erecting, inflatable thermal blanket for covering and bathing a person in a thermally-controlled inflating medium, comprising:

a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;

an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying 40 material sheet int a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers; and

means in an inflatable chamber and responsive to a 45 thermally-controlled inflatable medium for equalizing the temperature of said thermally-controlled inflating medium within said chambers;

wherein said means includes vent ports in said inflatable chamber, said vent ports through said overlaying flexible material sheet.

23. A self erecting, inflatable thermal blanket for. covering and bathing a person in a thermally-controlled inflating medium, comprising:

a flexible base sheet having two ends, two edges, and a plurality of apertures:

an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which extend substantially between said two ends an at least two continuous seams which extend substantially between said edges, said discontinuous and continuous seams forming said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers; and

means in a first inflatable chamber for equalizing the temperatures of said thermally-controlled inflating medium by circulating said thermally-controlled inflating medium within said chambers to said edges;

wherein said means includes an opening in said overlaying plastic sheet into said first chamber.

24. An inflatable, self-erecting thermal blanket for bathing a person in an inflating medium, comprising: a flexible undersheet;

the flexible undersheet including a layer of a first flexible material:

the flexible undersheet including a layer of a second flexible material bonded to the layer of first flexible material:

an overlaying, flexible material sheet attached to the layer of second flexible material by a plurality of discontinuous seams which form the overlaying material sheet into a plurality of communicating, inflatable chambers;

a plurality of apertures opening through the layer of first flexible material and the layer of second flexible material of the undersheet into the chambers;

means for admitting a thermally-controlled, inflating medium into the chambers; and

a vent port opening through the overlaying material sheet into one of the chambers for circulating a thermally-controlled, inflatable medium toward one of said edges.

PATENTAMT Weigstelle in Den Haag Recherchen- abteilung	EUROPF AN PATENT OFFICE Branch al The Hague Search Division	OFFICE EURC PEEN DES BREVETS Département à La Haye Division de la	P.B. 5818 Patentlaan 2 180 HV RIJSWIJK (ZH) Pays-Bas / Netherlands / Niederlande Telex 31651 (070) 40 20 40
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The Sea	rch Division approved the follow	ng items, as submitted by the a	pplicant:
	Abstract .	Title	√ Figure
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### **EUROPEAN SEARCH REPORT**

DOCUMENTS CONSIDERED TO BE RELEVANT				EP 88309191.0		
Category	Citation of document with	indication, where appropriate, nt passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. <sup>4</sup> )		
D,A	US - A - 4 572 18  * Abstract; co column 3, 1	38 (AUGUSTINE) Dlumn 2, line 64 - ine 50; fig. 1,2 *	1,6,7, 12	A 61 F 7/00 A 61 F 7/08		
Α	DE - A1 - 3 308 5		1			
Α	US - A - 3 714 9  * Abstract; f		1			
				TECHNICAL FIELDS SEARCHED (Int. CI.4)		
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	The present search report has b	een drawn up for all claims	1			
	Place of search	Date of completion of the search	1	Examiner		
	VIENNA	23-12-1988		TSILIDIS		

### CATEGORY OF CITED DOCUMENTS

- X : particularly relevant if taken alone
   Y : particularly relevant if combined with another
   document of the same category
   A : technological background
   O : non-written disclosure

- T: theory or principle underlying the invention
   E: earlier patent document, but published on, or after the filling date
   O: document cited in the application
   L: document cited for other reasons

# ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO.

EP 88 30 9191

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on 24/01/89. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A- 4572188	25-02-86	None		
DE-A- 3308553	20-09-84	US-A-	4718429	12-01-88
US-A- 3714947	06-02-73	None		
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DEUTSCHLAND

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**DEUTSCHES** 

**PATENTAMT** 

20. 9.84

(1) Anmelder:

Smidt, Udo, Prof. Dr.med., 4130 Moers, DE

② Erfinder: gleich Anmelder

Prüfungsantrag gem. § 44 PatG ist gestellt

(4) Kühl-Auflage für den menschlichen Körper

Die flächige Kühl-Auflage weist Durchströmungskanäle auf, die mit von einer Kühlmittelquelle zugeführtem Kühlmittel mit gegenüber der Körpertemperatur niedrigerer Temperatur durchströmbar ist.

Die Auflage kann die Form eines die zu behandelnden Körperpartien umschließenden Kleidungsstücks oder die Form einer Matte haben, auf welcher die zu behandelnde Person ruht bzw. mit welcher sie bedeckt wird.

- 3. Auflage nach Anspruch 2, dadurch gekennzeichnet, daß die Auflage (10) die Form eines die zu kühlenden Körperpartien bedeckenden Kleidungsstücks hat.
- 4. Auflage nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Auflage die Form einer Matte (14) hat, die auf die Matratze eines Bettes auflegbar bzw. in eine Bettdecke einziehbar ist.
- 5. Auflage nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die Durchströmungskanäle (12; 16) zwischen zwei thermoplastischen Kunststoffolien (26; 28) gebildet sind, die entlang der Begrenzungen der Durchströmungskanäle (12; 16) miteinander verschweißt sind.
- 6. Auflage nach Anspruch 5, dadurch gekennzeichnet, daß auf die Außenfläche der der zu kühlenden Körperpartie zugewandten Kunststoffolie (26) eine dünne Metallfolie (32), vorzugsweise eine Aluminiumfolie, aufkaschiert ist.
- 7. Auflage nach Anspruch 5 oder 6, dadurch gekennzeichnet daß auf der Außenfläche der der zu kühlenden Körperpartie abgewandten Kunststoffolie (28) eine Schicht aus wärmeisolierendem elastischem Material (34) aufgebracht ist.
- 8. Auflage nach Anspruch 7, dadurch gekennzeichnet, daß die wärmeisolierende Schicht (34) eine Schicht aus Schaumkunststoff oder Schaumgummi ist.

- 15. Auflage nach Anspruch 13, dadurch gekennzeichnet, daß die Kälteanlage eine nach dem Absorptionsverfahren arbeitende Kälteanlage ist.
- 16. Auflage nach einem der Ansprüche 1 bis 15, dadurch gekennzeichnet, daß in der Zuführ- (18) und/oder der Abführleitung (24) der Fühler je eines Temperatur Meß- oder Registrierinstruments vorgesehen ist.
- 17. Auflage nach einem der Ansprüche 1 bis 16, dadurch gekennzeichnet, daß in der Zuführ- (18) und/oder Abführleitung (24) der Fühler je eines die Durchflußmenge des Kühlmittels steuernden einstellbaren Thermostaten vorgesehen ist.
- 18. Auflage nach einem der Ansprüche 1 bis 17, dadurch gekennzeichnet, daß zusätzlich zu dem System der Kühlmittel-Durchströmungskanäle (12; 16) ein gegen- über diesem getrenntes System von Durchströmungskanälen mit gesonderter Zuführ- und Abführleitung für ein zweites Strömungsmittel mit von der Temperatur des Kühlmittels abweichender Temperatur vorgesehen ist.

Abfallwärme produzieren und abgeben und somit auch insgesamt weniger Energie verbrauchen. Da die Erzeugung von Wärme aber auch der Regelung und Aufrechterhaltung der Körpertemperatur dient, kann man sie durch Wärmeentzug intensivieren. Der Körper produziert Wärme auf zwei Wegen, nämlich einerseits durch Herabsetzung des Wirkungsgrades bestimmter chemischer Prozesse, wobei mehr Abfallwärme produziert wird, und zum anderen durch Muskelzittern, d.h. die periodische Kontraktion und Entspannung von Muskeln, wobei die hierfür erforderlichen energieliefernden chemischen Reaktionen ebenfalls Wärme erzeugen.

Ausgehend von der Erkenntnis, daß sich durch Wärmeentzug eine oder beide der vorstehend geschilderten Prozesse anregen lassen, und der Körper somit gezwungen wird, von der aufgenommenen und hauptsächlich in Form von Fettdepots gespeicherten Energie einen größeren Anteil in Wärme umzuwandeln, wird die gestellte Aufgabe erfindungsgemäß gelöst durch die Verwendung einer der oben beschriebenen Kühlkleidung funktionell ähnlichen, zum Entzug von Wärmeenergie aus oberflächennahen Partien des menschlichen Körpers mittels Durchströmung mit einem Kühlmittel geeigneten Auflage als Mittel zur Körpergewichtsreduktion.

Die zweckmäßig in der Größe der zu kühlenden Körperpartie entsprechend bemessene Auflage ist dabei vorzugsweise aus einem sich der Körperpartie anschmiegenden Material hergestellt, wobei sie in an sich bekannter Weise die Form eines die zu kühlenden Körperpartien bedeckenden Kleidungsstücks haben kann, welches von der zu behandelnden Person angelegt und während bestimmter Behandlungsdauern getragen wird.

vermag. Als Kältespeicher können beispielsweise zuvor in einer tiefgekühlten Atmosphäre, beispielsweise einer Kühltruhe, unterkühlte sogenannte "Kühlakkus" Verwendung finden.

Andererseits kann die Rückkühlvorrichtung auch ein an eine gesonderte Kühlvorrichtung angeschlossener Wärmetauscher sein, in welchem dem Kühlmittel die von den gekühlten Körperpartien aufgenommene Wärmeenergie entzogen wird. Im einfachsten Fall kann der Wärmetauscher in einem mit Wasser aus dem Leitungsnetz durchströmbaren Behälter angeordnet sein, wobei der Zu- und Abfluß des Wassers in diesen Behälter in Abhängigkeit von der Erwärmung der Wassertemperatur steuerbar ist.

Um die Durchströmung der Auflage mit dem Kühlmittel sicherzustellen, empfiehlt es sich dabei, in die Zuführleitung eine motorisch antreibbare Pumpe ein- bzw. der Zuführleitung vorzuschalten.

Alternativ kann die Auflage auch als Verdampfer in einen geschlossenen Kühlkreislauf einer Kälteanlage eingeschaltet sein, wobei die Kälteanlage entweder nach dem Kompressionsverfahren oder nach dem Absorptionsverfahren arbeiten kann.

In der Zuführ- und/oder der Abführleitung kann der Fühler je eines Temperatur-Meß- oder Registrierinstruments vorgesehen sein. Aus einem Vergleich der Eintritts- und der Austrittstemperatur in die bzw. aus der Auflage läßt sich dann unter Berücksichtigung der Menge und spezifischen Wärme des über die ebenfalls registrierbare Einschaltdauer und Förderleistung der das Kühlmittel

Die in Figur 1 gezeigte, als von einer zu behandelnden Person anlegbare Weste 10 ausgebildete erfindungsgemäße Auflage möge aus zwei Lagen einer flüssigkeits- und gasdichten thermoplastischen Kunststoffolie hergestellt sein, wobei die in der Zeichnung nur schematisch gestrichelt angedeuteten Durchströmungskanäle 12 durch Verschweißen der beiden Folienlagen entlang der Begrenzungen der Durchströmungskanäle entsprechend dem vorgegebenen Kanalmuster gebildet sein können. Wenn das Kanalmuster in einer der Folienlagenvoreingeprägt ist, kann die zweite Folienlage - und zwar zweckmäßig die später dem Körper der zu behandelnden Person zugewandte Lage - in ebenflächiger Form mit der mit dem geprägten Kanalmuster versehenen Folienlage verschweißt (oder verklebt) werden. Über wenigstens eine (nicht gezeigte) Zuführ- und eine Abführleitung ist ein flüssiges oder dampf- oder gasförmiges Strömungsmedium als Kühlmittel in das System der Durchströmungskanäle 12 einspeisbar und wieder aus ihm abführbar, wobei die Leitungen so am Kanalmuster angeschlossen sind, daß eine möglichst gleichmäßige und vollständige Durchströmung sämtlicher Kanale erfolgt. So kann die Zuführleitung beispielsweise im Bereich des unteren Randes und die Abführleitung im Bereich des Halsausschnittes jeweils auf der Rückseite der Weste am das Kanalsystem angeschlossen werden. Das Kühlmittel kann dann über die Leitungen von einem auf dem Rücken des Benutzers aufgeschnallten oder - über Verbindungsschläuche - auch von einem gesondert aufgestellten, d.h. weggebauten, Kühlmittelvorrat bzw. Kühlaggregat zu- und abgeführt werden. Die Umwälzung des Kühlmittels könnte - bei flüssigen Kühlmitteln im einfachsten Fall aufgrund des sogenannten "Thermosyphoneffekt" erfolgen. Eine genauere Steuerung der Durchströmungsmenge in Abhängigkeit von der über den Kühlmittelkreislauf abzuführende Körperwärme ist jedoch durch eine

ist, daß die Durchströmungskanäle 16 durch Vorformung oder Einprägung von kanalartigen Vertiefungen 30 in die körperabgewandte Folie 28 gebildet werden. Durch die ebenflächig auf die Folie 28 aufgelegte und entlang der Ränder der Vertiefung verschweißte körpernähere Folie 26 entstehen dann die geschlossenen Durchströmungskanäle 16. Auf die Außenfläche der Folie 26 ist eine dünne Aluminiumfolie 32 aufkaschiert, welche die flächige Wärmeaufnahme von den anliegenden Körperpartien verbessert.

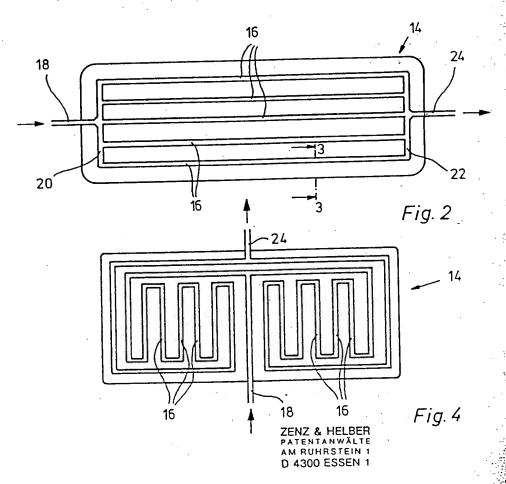
Auf der Außenseite der körperabgewandten Folie 28 ist dagegen eine dickere, wärmeisolierende Schicht 34 aus aufgeschäumtem Kunststoff, beispielsweise eine Polyurethan. Schaumschicht aufgebracht, welche neben der thermischen Isolierung der Durchgangskanäle 16 gegen Wärmeaufnahme aus der Umgebung auch einen Schutz gegen mechanische Druckbeanspruchungen der Durchgangskanäle bietet.

Im Falle der Ausbildung der Auflage als Kleidungsstück entsprechend der in Fig. 1 gezeigten Weste, kann diese wärmeisolierende Schicht 34 natürlich auch als von der Weste 10 getrennte, gesonderte Isolierwe-ste ausgebildet werden.

Die in Fig. 4 gezeigte, ebenfalls mattenförmige Auflage 14 entspricht der vorstehend in Verbindung mit den Figuren 2 und 3 besthriebenen Auflage 14 weitgehend mit der Ausnahme, daß die Durchströmungskanäle 16 nicht parallel und geradlinig von der einen zur anderen Schmalseite der Auflage, sondern in einem hiervon abweichenden, symmetrisch zur quer zur Mattenlängserstreckun verlaufenden Mittellinie der Auflage 14 ausgebildeten schleifenförmigen Kanalmuster ausgebildet sind, wobei die

Person subjektiv als unangenehm empfundene Gefühl der Unterkühlung der behandelten Körperpartien durch Aufwärmung nach der Behandlung schnell beseitigt werden.

Als Kühlmittel können Flüssigkeiten, z.B. Wasser oder Salzlösungen (Sole) Verwendung finden, die nach der Durchströmung der Auflage in geeigneter Weise rückgekühlt werden. Andererseits können auch die heute in Kälteanlagen in großem Umfang verwendeten und in Abhängigkeit von den Druck- und Temperaturbedingungen teilweise flüssigen und teilweise dampfförmigen Fluor-Kohlenwasserstoff-Kühlmittel direkt zur Durchströmung der Auflage verwendet werden, die dann funktionell dem Verdampfer einer Kühlanlage entspricht.



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11 Publication number:

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(12)

# **EUROPEAN PATENT APPLICATION**

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Priority: 05.10.87 US 104682 02.08.88 US 227189

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Designated Contracting States:
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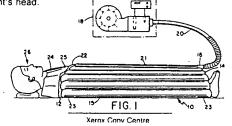
(2) Inventor: Augustine, Scott D. 1601 Stonecrest Court Blue Springs Missouri 64014(US) Inventor: Augustine, Douglas J 503 South 23rd Street Blue Springs Missouri 64014(US)

Representative: Cookson, Barbara Elizabeth et al WITHERS & ROGERS 4 Dyer's Buildings Holborn London EC1N 2JT(GB)

# Thermal blanket.

② A thermal blanket (10) includes an inflatable covering with a head end (12), a foot end (14), two edges (15) and an undersurface. The covering is inflated through an inlet (16) at the foot end (14) by a thermally-controlled inflating medium. An aperture array on the undersurface of the covering exhausts the thermally-controlled inflating medium from the covering. Exhaust port openings (23) are provided at the edges (15) of the covering to vent the inflating medium, which enhances circulation of the thermally-controlled medium through the cover. An uninflatable section (22) is provided at the head end (12), together with an absorbent bib (24) attached to the covering, adjacent the uninflatable section (22). When inflated, the thermal blanket (10) self-erects and provides a bath of thermally-controlled inflating medium to the interior of the erected structure. The enhanced circulation of the medium through the covers maintains a relatively high average temperature under the blanket (10) and a relatively uniform distribution of temperature in the inflating medium which is exhausted through the apertures into the structure's interior. When the structure covers a patient, the uninflatable section (22) provides a relatively unobstructed view of the patient's face, while the absorbent bib (24) maintains a relatively sanitary environment in the area beneath the patient's head.





## THERMAL BLANKET

### BACKGROUND OF THE INVENTION

This invention relates to thermal blankets used in a medical setting to deliver a bath of a thermallycontrolled medium to a patient.

The thermal blanket prior art is best expressed in our prior U.S. Patent No. 4.572,188 entitled "AIRFLOW COVER FOR CONTROLLING BODY TEMPERATURE." In our prior patent, a self-erecting, inflatable airflow cover is inflated by the introduction into the cover of a thermally-controlled inflating medium, such as warmed air. When inflated, the cover self-erects about a patient, thereby creating an ambient environment about the patient, the thermal characteristics of which are determined by the temperature of the inflating medium. Holes on the underside of our prior art airflow cover exhaust the thermally-controlled, inflating medium from inside the cover to the interior of the erected structure. Our airflow cover is intended for the treatment of hypothermia, as might occur post-operatively.

Evaluation of our airflow cover by skilled practitioners has resulted in general approbation: the opinion is that the airflow cover efficiently and effectively accomplishes its purpose of giving a thermally-controlled bath. We have realized, however, that, while our prior art airflow cover achieves its objective, certain improvements to it are necessary in order to realize additional clinical objectives and to enjoy further advantages in its use.

### SUMMARY OF THE INVENTION

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We have improved the clinical usefulness of our self-erecting airflow cover by observing that controlling the contour of its inflatable portion at its head end to define a generally concave non-inflatable portion will permit a care giver to more easily observe a patient's head, face, neck and chest. Further, we have observed that limited venting of the thermally controlled inflating medium from the edges of the cover results in more efficient, more uniform heating within the cover. We have also observed that it is good clinical practice to keep the area of the care site in the vicinity of the patient's head and face as clean as nossible

These three observations have resulted in an improved thermal blanket in which a self-erecting inflatable covering has a head end, a foot end, two edges, and an undersurface. An inflating inlet adjacent said foot end admits a thermally-controlled inflating medium into the covering. An aperture array on the undersurface of the covering exhausts the thermally-controlled inflating medium from the covering into the structure created when the covering self-erects upon inflation. The improvements to this basic structural complement include an uninflatable section at the head end of the covering, exhaust port openings at the edges of the covering, an absorbent bib attached to the covering at the head end adjacent the uninflatable section, and structural features that make the covering simple and economical to produce.

With these improvements, the thermal blanket, when inflated and erected over a patient, delivers the thermally-controlled inflating medium into the interior of the structure covering the patient, thereby thermally bathing the patient. The first improvement permits full viewing of the head and face of the patient from almost any aspect around the thermal blanket. The exhaust port openings increase the rate of circulation of the inflating medium within the blanket, thereby increasing the temperature within the structure and making the temperature distribution more uniform. The absorbent bib soaks up and retains liquids which might otherwise spread over the care site in the area of a patient's head. Such liquids can include the patient's own perspiration, blood, vomit, saliva, or liquids which are administered to the patient. The absorbent bib also acts to some extent to seal the head end of the inflated structure.

From another aspect, the invention is a thermal blanket for covering and bathing a person in a thermally-controlled medium. The thermal blanket includes a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures opening between the first and second surface of the base sheet. An overlying material sheet is attached to the first surface of the base sheet by a plurality of discontinuous seams which form the material sheet into a plurality of substantially parallel, inflatable chambers. A continuous seam is provided between the material sheet and the base sheet at the head end to form a non-inflatable viewing recess at the head end. Exhaust port openings are provided through the material sheet to vent the medium from the chambers away from the base sheet. An absorbent bib is attached to the head end in the vicinity of the viewing recess.

Therefore the invention accomplishes the important objective of providing a self-erecting, inflatable thermal blanket that permits a relatively unobstructed view of a patient's head and face when in use.

Another objective is the efficient and uniform heating of the interior of the structure created when the blanket is inflated with a heat inflating medium.

A signal advantage of the invention is the provision of such a blanket with a means for maintaining the cleanliness of the care site in the vicinity of the patient's head and face.

The advantageous simplified structure of the thermal blanket make its production straightforward and economical.

These and other important objectives and advantages will become evident when the detailed description of the invention is read with reference to the below-summarized drawings, in which:

Figure 1 is a side elevation view of the thermal blanket in use, with associated thermal apparatus indicated schematically;

Figure 2 is an enlarged top plan view of the thermal blanket opened flat;

Figure 3 is an enlarged sectional view taken along 3-3 of Figure 2;

Figure 4 is a further enlarged sectional view taken along line 4-4 of Figure 3; and

Figure 5 is a partial underside view of the thermal blanket.

# DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

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When used herein, the term "thermal blanket" is intended to be interchangeable with, but not necessarily limited by, the term "airflow cover" used in our U.S. Patent No. 4,572,188, which is incorporated herein in its entirety by reference. In this description, the term "thermal blanket" is meant to invoke a self-erecting, inflatable structure for delivering a thermally-controlled inflating medium to the interior of the structure created when the thermal blanket is inflated. The purpose of the thermal blanket is to efficiently administer a uniformly thermally-controlled bath of the inflating medium to a patient within the erected structure.

Our invention is illustrated as we intend for it to be used in Figure 1. In Figure 1, a self-erecting, inflatable thermal blanket 10 has a head end 12, a foot end 14 and two lateral edges, one indicated by 15. An inflation inlet cuff 16 is connected to a heater/blower assembly 18 which provides a stream of heated air through a connecting hose 20. When the heater/blower 18 is operated, the stream of heated air flows through the inflating hose 20 into the thermal blanket 10 through the inflation cuff 16. When the blanket is inflated, it erects itself into a Quonset hut-like structure with a quilted upper surface 21. As described below, a pattern of apertures on the undersurface of the blanket (not shown in Figure 1) delivers the inflating heated air into the interior space enclosed by the erected thermal blanket.

The contour of the inflatable portion of the thermal blanket 10 is varied at the head end 12 of the blanket to provide a non-inflated blanket recess 22 in the quilted upper surface 21, which remains smooth and flat when the blanket is inflated and erected. Circulation of the heated air is accelerated through the thermal blanket by exhaust port openings in the upper surface, adjacent the lateral edges of the blanket. Two exhaust port openings are indicated by reference numeral 23. Further, a bib 24 made of an absorbent material is attached to the head end 12 of the thermal blanket in the vicinity of the non-inflated recess 22. In fact, as shown in Figure 1, the bib 24 includes a semi-circular tab 25 that extends into the recess 22.

As illustrated in Figure 1, the thermal blanket of the invention is inflated, erects itself into a bathing structure, and bathes a patient 26 with the thermally-controlled air used to inflate the structure. While the patient is being thermally bathed, the uninflated recess 22 permits observation of the patient's head, face, neck, and chest from almost any location with respect to the thermal blanket 10. Thus, if the patient is placed on a gurney or a bed, the head of which is against a wall, a care giver such as a nurse, intern, resident, or doctor, can keep the patient's face under observation from the foot end 14 of the thermal blanket 10. Respiration can be detected by the rise and fall of the bib and uninflated area, which rest directly on the patient's chest. Moreover, the bib 24 will provide an absorbent sink for stray, unconfined liquids in the area of the patient's head or at the head end 12 of the thermal blanket 10.

Figure 2 is a plan view of the thermal blanket 10 opened flat to show details of its structure. Figure 2 illustrates the upper surface of the thermal blanket, that is the side that is visible in Figure 1. As seen, the upper surface consists of a parallel array of elongated tubes of which 30 and 32 are the lateralmost tubes, 34 is the center tube, and the tubes 38 are arrayed between one of the lateralmost tubes and the center tube. Each tube is separated from an adjacent tube by a discontinuous seam, one of which is indicated by 40. The seam 40 separates the tube 32 and its nearest adjacent neighbor 38. The discontinuous seam 40 is

interrupted by passageways 42 communicating between the tubes. An interrupted seam separates every tube from one adjacent neighboring tube. The seams permit the thermal blanket, when inflated, to assume a tubular structure on the upper surface, while the ports 42 permit full circulation of the inflating medium throughout the array of tubes. The foot-end seam 45 is continuous. The tubes are inflated through the center tube 34 which transitions to a port 36, through which the inflation cuff 16 is inserted. The edge seams 43 are discontinuous only at the exhaust port opening locations 23. A seal can be made between the inflation port 36 and the inflation cuff 16 by any conventional means, for example, an O-ring, or even tape. When the inflating medium is introduced into the center tube 34, it flows laterally from the center tube into all of the other tubes through the ports 42. Near the head end 12, a continuous seam 40 defines the forward end of all of the tubes, with the seam assuming a bell-curve shape. On the head end side of the seam 40, the thermal blanket 10 is uninflatable. The bell-shaped seam 40 thus defines the uninflatable area 22 at the head end of the thermal blanket 10, which is essentially coplanar with, or substantially parallel to, the underside of the blanket. As shown in Figure 1, by virtue of its structural integration with the rest of the thermal blanket 10, the non-inflated recess extends over the upper chest of the patient 26 when the blanket is inflated. However, since the recess 22 is uninflated, it provides a wide-angled viewing gap in the inflated contour of the upper surface 21. The gap is filled by continuation of the underside of the blanket. It is also noted that the pattern of inflatable tubes can be replaced by other suitable patterns of communicating, inflatable chambers. The tubes are preferred since they impart strength and shape to the erected bathing structure; other inflatable structures are contemplated, however.

The absorbent bib has an indent 43 cut into its outside edge, which permits the blanket to be drawn up to the chin of a patient and which provides absorbency laterally up the neck of the patient. The absorbent bib can consist of any absorbent material such as a single- or multi-ply tissue paper which is used to make paper towels.

Construction details of the thermal blanket 10 are illustrated in Figures 3 and 4. The thermal blanket 10 is assembled from a base sheet consisting of an underside layer 50 formed from flexible material capable of bonding to a layer 52 of heat-sealable plastic. For the layers 50 and 52, we have used a stratum of absorbent tissue paper prelaminated with a layer of heat-sealable plastic. Material of such construction is commercially available in production rolls and is used to make painters' drop cloths. The upper side of the thermal blanket consists of a sheet of plastic bonded to the plastic layer 52 by an interruptible heat-sealing process to form the interrupted seams, one of which is indicated by 54, and the inflatable tubes, one indicated by 55. As can be seen in Figure 3, the interruption of the seam 54 forms a passageway 56 between adjacent tubes 55 and 57.

The absorbent bib and tab are shown in Figure 3 as a single material layer 60/58. Alternatively, they may be formed from separate material sheets cut to the outlines illustrated in Figure 2. The absorbent material forming the bib and tab can be bonded to the upper plastic layer by heat process or by gluing.

The inventors also contemplate deletion of the bib and tab. In this instance, the thermal blanket would still have the viewing recess, which would be defined by the continuous seam at the head end, and which would be filled with the forward portion of the base sheet.

Circulation of heated air through the blanket is enhanced by the exhaust port openings 23, which open through the upper plastic sheet sheet, which is heat sealed to the base of the blanket. The openings 23 vent the heated inflating air out of the outermost tubes 30 and 32, away from the underside of the blanket. Because air can circulate to, and through, the blanket edges, the inflating air in the outermost tubes is hotter than if the openings were absent. This results in hotter air being delivered through the underside apertures toward the edge of the blanket. We have measured the temperature distribution within the thermal blanket for inflating air which is heated to a medium temperature range and for inflating air which is heated to a high temperature range. The results are provided in Table I for a blanket consisting of 13 tubes. Measurements of the temperature of air exhausted through underside apertures were made on the underside of each tube on one side of the blanket. The tubes are numbered 1-6, with 1 being the tube adjacent to the center tube, and tube 6 being the outermost tube adjacent on lateral edge of the blanket. Test apertures were made in the bottom of tube 6 only for the purposes of this test. As is evident, the distribution of temperature within the erected thermal blanket is more uniform when the exhaust port openings are provided. Further, provision of the exhaust ports also increases the average temperature within the erected structure of the blanket. Clearly, the provision of exhaust port openings at the lateral edges of the blanket delivers results which one would not expect when considering the operation of our thermal blanket with no exhaust port openings.

In our preferred embodiment, the exhaust port openings are slits in the edge seams of our blanket. These slits vary in length from 1-3/4 to 2 inches. Each edge seam is discontinuous approximately at each corner of the blanket so that inflating air is vented away from the underside of the erected blanket. This

keeps the relatively "colder" air at the blanket edges from mixing with the relatively "hotter" air exhausted into the structure through the underside apertures. The result is a "flatter" temperature profile of air within the blanket than without the vents, which raises the average temperature within the erected structure and makes the temperature distribution in the structure more uniform. Resultantly, the clinical effect of the blanket is enhanced. Heating is better controlled, and more uniform, with greater comfort to the patient.

TABLE I

10	TUBE NO.	MEDIUM TEMPERATURE RANGE		HIGH TEMPERATURE RANGE		
		WITHOUT EXHAUST PORTS	WITH 2" EXHAUST PORTS	WITHOUT EXHAUST PORTS	WITHOUT 2" EXHAUST PORTS	
15	center (inlet) tube Tube #1 Tube #2 Tube #3	113.3 F. 109.9 105.3 103.2	114.1 F. 112.3 109.8 107.1	121.3 F. 117.3 113.4 111.0	121.3 F. 117.7 115.0 113.3	
20	Tube #4 Tube #5 Tube #6 (outermost) Average temp. under cover	99.9 97.2 85.2 103.8	104.3 100.0 95.8 106.7	101.4 95.7 89.6 108.4	108.6 104.4 99.4 112.5	

The thermal blanket of the invention is enabled to bathe a patient in the thermally-controlled inflating medium introduced into the upper side tubes by means of a plurality of apertures 62 shown in Figures 4 and 5. The apertures extend through the underside of the blanket, which includes the layers 50 and 52. The apertures 62 are made in the footprints of the tubes of the blanket upper side according to a pattern which has been determined to deliver a very uniform thermal bath. In this regard, no apertures are provided through the underside into the lateralmost tubes 30 and 32, or into the center tube 34. In addition, the apertures 62 are provided through the underside to the apertured tubes in a density which varies inversely with the proximity of the tube to the center tube 34. Thus, the hole density increases from the tube 38a through the tube 38d. Even with the exhaust port openings, the temperature of the inflating medium exhibits a drop from the center to the lateralmost tubes. The varying density of the apertures 62 tends to reduce this gradient further by forcing hotter air to the edges of the blanket. Thus, the thermal bath delivered to the patient is of a generally uniform temperature. The aperture density variation also equalizes the flow of inflating medium out of the apertures. As will be evident, the inflating pressure will be greatest at the center tube 34 and will tend to diminish toward the lateral edges of the thermal blanket. Therefore, fewer apertures are required for the tubes near the center tube 34 to deliver the same amount of air as the relatively greater number of apertures in the tubes at a greater distance from the center tube 34.

The apertures comprise openings which can be of any appropriate shape. For example, we have produced blankets with elongated apertures, approximately 1/7 inch in length.

Many modifications and variations of our invention will be evident to those skilled in the art. It is understood that such variations may deviate from specific teachings of this description without departing from the essence of the invention, which is expressed in the following claims.

# Claims

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- A thermal blanket (10) for covering and bathing a person in a thermally-controlled inflating medium, comprising:
- a flexible base sheet having a head end (12), a foot end (14), two edges (15), and a plurality of apertures (62);
- an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams (40) which form said overlaying material sheet into a plurality of communicating, inflatable chambers (30,32,34,38), said apertures (62) opening through said base sheet into said chambers; and

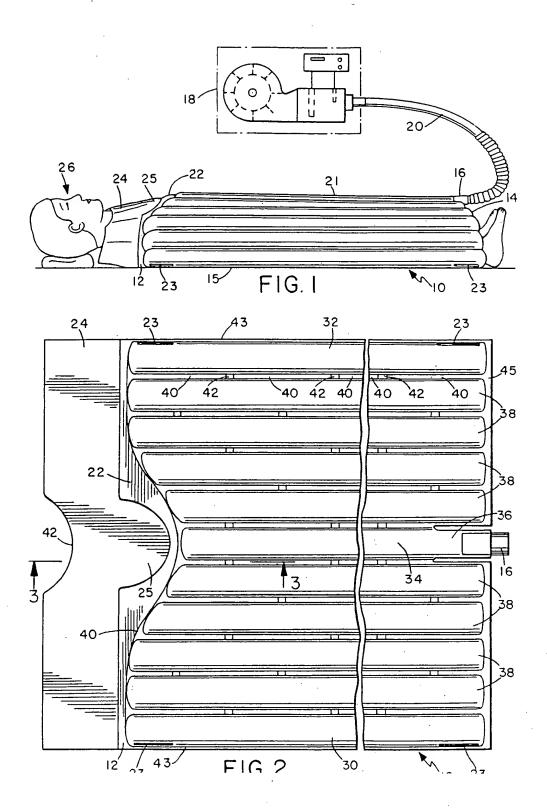
a continuous seam (40) between said overlaying material sheet and said base sheet at said head end which forms a non-inflatable viewing area (22) in said blanket at said head end, said non-inflatable viewing area (22) being substantially coplanar with, or parallel to, said base sheet.

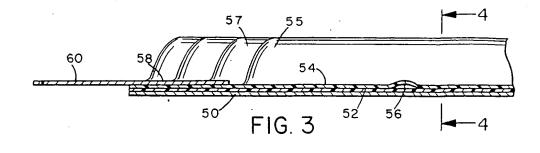
- 2. The thermal blanket of claim 1, wherein said base sheet includes an undersheet of flexible fibrous material (50) and a sheet (52) of plastics material coextensive with and attached to said undersheet.
- 3. The thermal blanket of claim 1, wherein said base sheet includes a multi-layered structure in which the bottommost layer is a paper sheet (50) bonded to an upper sheet (52) of plastics material.
- 4. The thermal blanket of claim 2 or 3, wherein said discontinuous seams (40) are substantially elongate, heat-formed seals between said overlaying material sheet and sheet of plastics material.
- The thermal blanket of claim 2, 3 or 4, wherein one of said discontinuous seams (40) includes a sequence of collinear, heat-formed seals extending from said foot end to said head end.
- 6. The thermal blanket of any one of the preceding claims, wherein said plurality of discontinuous seams form said overlaying material sheet into a plurality of mutually parallel, communicating tubular chambers (30,32,34,38).
- 7. The thermal blanket of any one of the preceding claims, including an exhaust port opening (23) through said material sheet adjacent one of said edges for venting an inflating medium from said chambers and away from said base sheet.
- 8. The thermal blanket of any one of the preceding claims, including a patterned array of apertures (62) opening through said base sheet into said chambers (30,32,34,38), said patterned array comprising a density pattern in which the density of said apertures increases toward at least one of said edges (15).
- 9. The thermal blanket of claim 8 when dependent on claim 6, wherein one of said tubular chambers (34) is centrally positioned in said parallel tubular chambers and said density increases from said centrally positioned chamber (34) toward at least one of said edges (15)
- 10. The thermal blanket of claim 9, wherein no apertures open through said base sheet into said s centrally positioned tubular chamber (34).
  - 11. The thermal blanket of claim 10, wherein no apertures open through said base sheet into a tubular chamber (30,32) adjacent one of said edges.
  - 12. The thermal blanket of any one of the preceding claims, comprising an inflating inlet (16) adjacent said foot end (14) for admitting a thermally-controlled inflating medium.
- 13. The thermal blanket of any one of the preceding claims, including an absorbent bib (24) attached to the head end of said base sheet.

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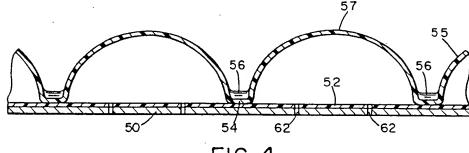


FIG. 4

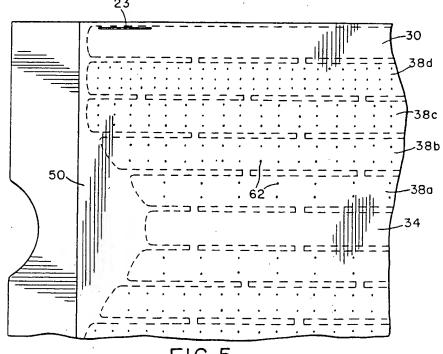


FIG 5

# **EUROPEAN SEARCH REPORT**

	DOCUMENTS CONSIDERED TO BE RELEVANT			EP 88309191.0		
Category	Citation of document wi of rele	th indication, where appropriate, vant passages	_	Relevant to claim	CLASSIFICATION APPLICATION	
D,A	US - A - 4 572 1	88 (AUGUSTINE)		1,6,7,	A 61 F	7/00
	* Abstract; c	column 2, line 64 ine 50; fig. 1,2	*	12	A 61 F	7/08
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Place of search		Date of completion of the search			Examiner	
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- X : particularly relevant if taken alone
   Y : particularly relevant if combined with another document of the same category
   A : technological background
   O : non-written disclosure
   P : intermediate document

- after the filing date

  D: document cited in the application
  L: document cited for other reasons
- & : member of the same patent family, corresponding document

# Ninth New Collegiate Dictionary

a Meriam-Webster

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their time derivatives and that a solutionial energy and kinetic energy are HAMILTONIAN [11784]: a small lake or pond - 1 statement of the solution of the sol

language of West Punjab
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Ham-l-nate \-not. -,nāt\ adj (1668) 1: consisting of laminae 2: bearing or covered with laminae

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national national

lamp-post \lam(p\).pöst\ n (1790): a post supporting a usu. outdoor lamp or lantern lamp-press. The lamp-prey \lamper

# Webster's Third New International Dictionary

OF THE ENGLISH LANGUAGE
UNABRIDGED

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MADE IN THE UNITED STATES OF AMERICA 38Kp85

bombing pres part of 80MB bombing run n: 80MB RUN bombing run n: 80MB RUN bomb ketch n: a small strongly built ketch baving mortars mounted for use in naval bombardmentu bomb lance n: a harpoon with an explosive head bomb-line \(\frac{1}{2} \cdot \cdot \), s is demarcation line established in a combatt area borond which aircraft can arease (as by bombing) without danger to their descriptions are strated to the strength of the

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John of the processed there is a warehouse insured against loss or damage to goods stored therein by thom der; blands(ft) n - s [bond - ter] 1: one that bonds; as a : an assembler of electromagnet laminations b: 1 worker who welds copper bonds between the joints of ratio 2: BONDSTONE 1 Bonder, ft. O'N böndi- more at BOND 1: A Norwesian or 1 should; a store to be a store of the store of th

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# Science & Technolog

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Molecule	Name Angle Value
_ <del></del>	Water → H O H (% 105*)
· SO <sub>2</sub>	Sulfur dioxide 1964 O S O 119°
CO,	Carbon dioxide - O-C-O 180°.

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Theoretical calculation. Ouantum mechanics can, in principle, be used to calculate bond lengths and angles accurately by solving the appropriate quantummechanical equations, although such calculations for large molecules are extremely difficult and require a great deal of computer time. A number of simple theoretical concepts have been developed that have some approximate correlation with experimentally determined bond angles and distances. One is called the electrostatic or valence-shell electron-pair repulsion model. It treats a chemical bond as a shared pair of electrons which repels other pairs associated with the ory means a cheralternative model, valence-bond theorbitals centered on the bonded anyerlap of electronic brid orbitals centered on the same atoms have a characteristic geometry. See Chemical structures; Quan-TUM CHEMISTRY; VALENCE.

Bruce A. Garetz Bibliography. J. H. Callomon et al., Structure Data of Free Polyatomic Molecules, vol. 7 of Landolt-Bornstein, Group II, Atomic and Molecular Physics, 1976; M. D. Harmony et al., J. Phys. Chem. Ref. Data, 8:619-721, 1979; K. P. Huber and G. Herzberg, Constants of Diatomic Molecules, 1979; I. Levine, Physical Chemistry, 3d ed., 1988; J. N. Murrell et al., The Chemical Bond, 2d ed., 1985; L. Pauling, The Nature of the Chemical Bond, 3d ed., 1960.

## **Bonding**

with a method of holding the parts of an object together "ithout the aid of an adhesive such as an epoxy or a reinforced planaglue. Composite materials such as fiberbetween the re-nite ics require strang interfacial bonding between the re-nite ics require and the matrix. In the case of atomic or optical contact bonding, interatomic forces hold the pi bonding, surface flat: urts together. In optical contact mating parts determine ness and cleanliness between the atoms at the surface pro. • the bonding strength, and the number of valence electron wide the necessary forces. The determines the bonding strer. is in the atoms of a material atoms which constitutes a molt ligth between the group of term chemical bonding is used. cule. In these cases the SEE ADHESIVE: CHEMI-CAL BONDING; COMPOSITE MATERIAL.

Wire bonding is an interconnec used in microchip manufacturing to of an integrated continuity between the metal pads of the package circuit chip and the electrical leads thods of wire housing the chip. The two common me sonic bondbonding are thermocompression and ultra e is bonded ing. In these, a fine aluminum or gold wir ited circuit at one end to the metal pad of the integra chip, and at the other to the electrical lea package. There are three types of thermocom, ression bonds: wedge, stitch, and ball. In thermocompi "sion bonding, a molecular metallurgical bond is formed at the two metal junctions-bond wire and IC metal

pad, and bond wire and package lead metal—by applying heat and pressure without melting. In ultrasonic bonding, the molecular metallurgical bond is achieved through a combination of ultrasonic energy and pressure. The bonding operation is done under pressure to break the few surface layers of the material and form the bond between the contamination-free surfaces. Thermocompression bonding has higher throughput and speed than ultrasonic bonding. The bonding wire is usually aluminum, which does not introduce any intermetallic problems. See Circuit (ELECTRONICS): INTEGRATED CIRCUITS.

Lakshmi Munukutla

# Bone

The hard connective tissue that, along with cartilage, forms the skeleton of vertebrates. SEE CONNECTIVE TISSUE. For a detailed discussion of the histology of bone SEE SKELETAL SYSTEM.

Bone is a complex substance with remarkable abilities of structural adaption. One of the functions of bone is structural. It forms the skeleton, which proganism mechanical support and protection for the organism. During support and protection for the organism to adapt its form and structure for this function. See Muscular System.

The other major function of bone tissue is metabolic. It maintains a mineral homeostasis in the organism by regulating the concentrations of key blood electrolytes, including calcium. The parathyroid glands are essential for this regulation. Calcium is necessary for nerve conduction, muscle contraction, clot formation, cell secretion, and other metabolic activities. See Calcium metabolism: Parathyroid Gland.

Composition and microstructure. Bone tissue, the material of which whole bones are made, consists of cells in an extracellular matrix. The cells are numerous and biologically very important, but since they occupy such a small volume, bone tissue is, effectively, the extracellular matrix. This matrix has two principal ingredients, collagen and an inorganic mineral phase called apatite or hydroxyapatite consisting primarily of calcium phosphate crystals. The apatite When the mineral is removed from bone tissue; the demineralized matrix is mostly collagen and loses its stiffness. See Apartite: Collagen.

At the macroscopic level there are two major forms of bone tissue, compact (cortical) and spongy (calcellous/trabecular). Compact bone, a dense material with a specific gravity of about 2, forms the outer shell of all bones. Spongy bone exists at the ends of long bones, within the vauk of the skull, and generally within the confine of a cortical bone shell. The short with both of bone in spongy bone are trabeculee.

At the microstructural level, both sporgy bone and compact bone have a lamellar organization. The trabulae of spongy bone generally are composed of a collection of more or less parallel /amellae. In compact bonthe lamellae may be arranged either in parallel fasion or concentrically in quasicylindrically shaped structures called osteons (Haversian systems). The circumferentially arranged parallel lamellae are found hear the outer and inner surfaces of the compact bone. These two different types of normal wellorganized compact bone tissue are called lamellar and osteonal. The greatest volume of the compact bone is

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